GDSN for the FDA Global Unique Device Identifier Database (GUDID)

Implementation Guide

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Change Log

Issue No.	Date of Change	Changed By	Summary of Change
1	9 September 2013	Pete Alvarez	Merger of sections created by Pete Alvarez (Global Office) and Scott Brown (GS1 U.S.)
2	6 January 2014	Scott Brown	Updated section, GDSN to GUDID Attribute Mapping and Guidance on Populating Attributes per latest FDA GUDID requirements and User Guide
3	8 January 2014		Final Review prior to submitting into the GSMP

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1. Introduction

1.1. Purpose of this Document

The purpose of this document is to explain how to use the Global Data Synchronization Network (GDSN) to securely provide data to a Unique Device Identification (UDI)) database. The first version of this implementation guide will focus on the U.S. FDA Global Unique Device Identifier Database (GUDID) requirements since this is the only regulator to issue a UDI rule for medical devices as of this writing. As other regulators introduce UDI regulation this document will be updated as needed.

1.2. Who Will Use this Document?

This document is intended primarily for medical device manufacturers who have decided to use GS1 standards to comply with UDI regulation and the GDSN Data Pools who will be required by the medical device customers to provide data on their behalf to a UDI database.

The guidance and GDSN attributes included in this document is based on the published database requirements and GUDID Users' Guide from the U.S. FDA, plus the lessons learnt from the GDSN pilot held as part of the U.S. FDA User Acceptance testing of 2012. This document contains addition guidance on Master Data Management and Governance plus Information Lifecycle Management and Data Quality. This information is intended as general guidance for the purpose of assisting GS1 members. The UDI regulation may contain specific information related to the rule, which in case of conflict supersedes this general guidance.

1.3. Prerequisite

It is assumed that the reader is already familiar with the UDI regulation and the database requirements prior to using this implementation guide. For additional information on UDI visit the GS1 UDI webpage or the website of the specific regulation in question.

Below are a few basics steps the Medical Device manufacturer should consider prior to using the GDSN to register their medical device product data in the appropriate UDI database. The section includes prerequisites for using GS1 standards to implement a UDI regulation.

1.3.1. The GS1 Global Company Prefix (GCP)

The GS1 Global Company Prefix is the base component used to create a GS1 Key such as a Global Trade Item Number (GTIN). The GS1 Global Company Prefix is a license to create GS1 Keys and is issued by any one of the GS1 Member Organisations to companies who wish to use the GS1 system.

The GS1 website lists 10 basic steps to bar code implementation and is offered as a guide for getting started. For additional information regarding your GS1 Company Prefix and GS1 standards contact your local GS1 Member Organisation by visiting the GS1 website.

1.3.2. Role the Global Trade Item Number (GTIN) and Application Identifiers (AIs)

The Global Trade Item Number (GTIN), as the GS1 trade item "Identification Key", is used to identify medical devices, identifying different product variants and each package configuration to achieve unique and unambiguous identification. The UDI includes at a minimum the "static" portion, a "Device Identifier" (DI), as its "key" to specific device related information stored in a database. The GTIN is the GS1 solution for creating the Device Identifier component of a UDI and accessing medical device information stored in a database.

The Unique Device Identifier also includes a 'dynamic' portion, known as the "Production Identifier", to represent production control information generated as part of the manufacturing process based upon

the specific medical device. This Production Identifier (PI) can include, for example, manufacturing date, expiry date, lot number or serial number. GS1 Application Identifiers (AIs) are the GS1 solution for creating the Production Identifier component of a UDI.

Note: the Production Identifier portion of a UDI is NOT stored in a UDI database.

Additional information regarding the use of the GS1 GTIN and Application Identifiers can be found in the GS1 General Specifications, GS1 Healthcare GTIN Allocation Rules and GS1 UDI support materials (http://www.gs1.org/healthcare/udi).

1.3.3. Automatic Identification and Data Capture (AIDC) Marking

Marking of the UDI on the medical device packaging (and in some cases the medical device itself), via an Automatic Identification and Data Capture (AIDC) "Data Carrier" technology is a primary requirement of the U.S. FDA UDI ruling. The Data Carrier is the means used to transport the UDI with the medical device and retrieve its unique identification, enabling access to the database stored information. The GS1 System includes specifications for the use of both Bar Code and RFID Data Carriers including (but not limited to) EAN/UPC, GS1-128, GS1 DataMatrix Bar Code symbologies.

Selection of the appropriate GS1 Data Carrier is based upon a number of factors including the UDI to be encoded in the Data Carrier, the distribution channel of the medical device, available space for the Data Carrier among other criteria of the regulation. Additional information and specifications on the selection and use of GS1 Data Carriers can be found in the GS1 General Specifications and GS1 UDI support materials (http://www.gs1.org/healthcare/udi).

For additional information on identification of items below the "each" level refer to the GS1 Healthcare GTIN Allocation Rules (http://www.gs1.org/1/gtinrules/index.php/p=static/t=healthcare)

1.3.4. The role of Global Location Number (GLN) in UDI

The Global Location Number is a 13 digit numeric GS1 standard used to identify locations and legal entities. While the U.S. FDA UDI regulation does not require the use of GLNs in order to comply with the rule, it is required when using the Global Data Synchronisation Network (GDSN) to identify the manufacturer and the data recipients. In addition, the U.S. FDA Global UDI database is identified by GLN 1100001017041 within the GDS Network. This unique identification ensures that there is a single and unique global identification of the U.S. FDA GUDID within the entire GDS Network for all Data Pools to use in the submission and registration of the manufacturer's medical device product data.

1.3.5. GDSN Knowledge

This guide and the information contained within it require the reader to have a basic understanding of the Global Data Synchronisation Network (GDSN). For more information on the GDSN refer to the GDSN page on the GS1 website or contact a GS1 member Organisation or a GDSN certified Data Pool.

1.4. What is UDI and (G)UDID

The Unique Device Identifier (UDI) is a multinational initiative driven by several medical device regulators with the intention of improving patient safety and healthcare business processes. Each UDI regulation is expected to include a database, which will contain medical device product data. This is referred to as a Unique Device Identifier Database (UDID). For more information in UDI at a global level and how GS1 standards support it refer to the UDI page on the GS1 website. The illustration below provides a basic cross reference between UDI terms and the corresponding GS1 standard.

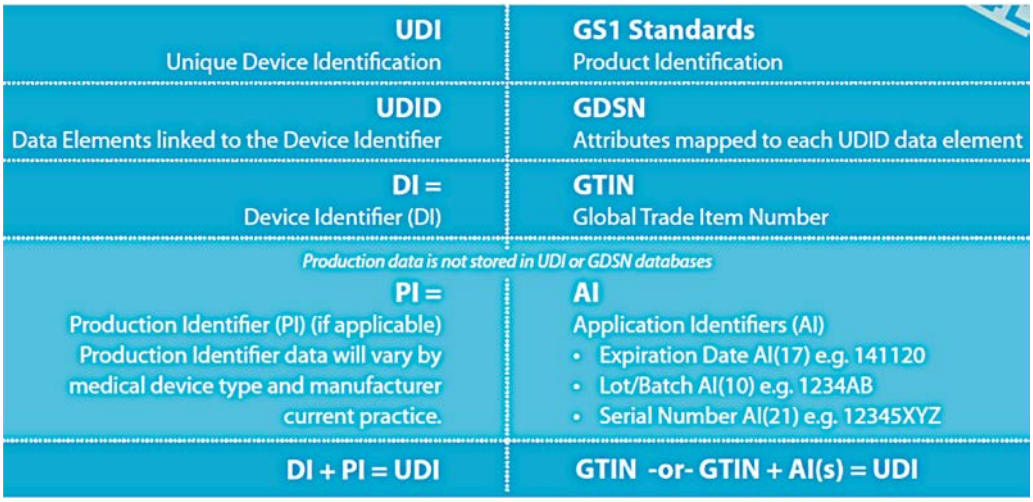

Illustration1

The United States Food and Drug Administration is the first regulator to issue an UDI rule. In addition the U.S. FDA operates a database called Global Unique Device Identifier Database (GUDID) designed to store medical device product data. For more information on the U.S. FDA UDI and GUDID and how GS1 standards support it refer to the UDI page on the GS1 US website.

1.5. Master Data Management and Governance

One of the most challenging areas related to implementation of the UDI regulation is the Master Data Management and Governance. Master Data Management and Governance (MDM&G) refers to a series of processes and protocols that should exist within an organisation to create, enrich, maintain and publish product information within and outside the enterprise. Equally important is “data quality management,” which is a complementary cycle of activities aimed to ensure that the subject information meets high standards of quality and reliability. In short, the data created by the product manufacturer must meet the requirements of the intended use case. Medical device data which has to comply with UDI regulation is no exception.

Completeness and accuracy of product data is the responsibility of the manufacturer. Each manufacturer should have an internal process to manage the data required by the regulator. This includes:

- data quality checks and procedures
- data management process and policies
- enterprise-wide data governance policies
- roles and responsibilities which outline who has the authority to create, modify and approve the data

GS1 strongly recommends that each manufacturer ensure they have a robust Information MDM&G and data quality process in place as part of their internal data preparation process.

1.6. Data Quality

Good data quality is a key ingredient of any efficient supply chain. Having the means to continuously maintain high quality data is not only vital to reducing errors and improving patient safety but also to reducing errors in the supply chain. It is also fundamental to increasing efficiency, reducing costs and positively impacting customer satisfaction.

Good quality data means that all master data is complete, consistent, accurate, time-stamped and industry standards-based. By improving the quality of data, trading partners reduce costs, improve productivity and accelerate speed to market.

For more information on GS1 data quality best practices and recommendations refer to the Data Quality page on the GS1 website

Some regulators may include specific business and data validations to ensure data quality of the information provided by the manufacturer. Please refer to the specific regulation for more information.

1.7. Data Management

Data Management refers to processes and procedures within an enterprise related to lifecycle information management. In relationship to UDI regulation, this refers to product master data and lifecycle management of the related information. The U. S. FDA regulation contains specific data management requirements and recommendations to which a manufacturer must adhere. However, this section contains general guidance as a recommendation to augment the requirements of any regulator. In case of conflict, the regulation supersedes this guidance.

Below are seven basic steps of an information lifecycle management process.

1. Create, Import or Receive

The first step is the creation of the product data. This may include gathering information related to the product specifications, raw materials, function, regulatory requirements, and sterilization among other areas. The U.S. FDA GUDID includes a specific list of data requirements and data relationship based on the recommendation from the International Medical Device Regulators Forum (IMDRF), formerly known as the Global Harmonization Task Force plus additional information required by the U.S. FDA. In this step the manufacturer should confirm the core attributes and match against data requirements of the UDI regulation. Sections 3 and 4 of this document contain a listing of the GUDID data requirements and cross reference to GDSN attributes. The U.S. FDA UDI rule and Users Guide supersedes any information found in this document and will always serve as the point of reference for U.S. FDA UDI requirements.

2. Enrich and Validate

This step refers to an internal process by which the data created in step one is completed with any missing data, validated for compliance with specific requirements of the UDI regulation and approved. This is a fundamental step in data quality management. GS1 offers general data quality guidance and best practices based on industry experience including the GS1 Data Quality Protocol. Below are a few basic steps to consider.

- Completeness: Is data missing which is needed for that specific product?
- Accuracy: Is data precise, correct, and current?
- Conformity: Have formatting rules and standards been applied properly?
- Logic: Is data valid or conflicting across product classes?
- Consistency: Is data consistent across systems for the same field?
- Integrity: Are there appropriate data linkages between internal systems?
- Duplication: Are there unnecessary representations of the same data?

For specific information regarding data quality and validation requirements of the U.S. Global UDI Database refer to FDA regulation and User Guide.

3. Publish and Activate

Once the data is created, enriched, validated and approved it can be published and activated for use. Publication can refer to internal users, catalogs or the GDSN Source Data Pool for data synchronization with external users.

In relationship to UDI, the data should now be ready for registration in the corresponding UDI database, such as the U.S. FDA GUDID. Section two of this document outlines three ways for registering data with the U.S. FDA's GUDID, including how to use a GDSN Data Pool to register the data on behalf of the manufacturer.

4. Audit and Evaluate

Part of the information lifecycle management includes routine monitoring to ensure the data is fit for purpose. This is typically an ongoing process, which is part of a continuous data quality management and improvement process. It can be in the form of an actual audit event, but generally it is part of the user feedback process as a result of application of the information. Ideally the Audit is performed against a set of Metrics or Key performance Indicators. Error investigation should include a route cause analysis to determine the cause of the problem and steps to prevent it from re-occurring. Some organizations include a scorecard to report performance and track improvements over time.

5. Update and Maintain

The information lifecycle management process should include a step to update information as relevant changes occur in any part of the master data. This applies to information about the product as well as well as the organization. This step should include notification of the change to the data owner for approval.

6. Inactivate and Archive

As information is obsoleted and purged, it should be removed from active use. This may include a flag to indicate that a particular data element is inactive and is no longer used, but it is not removed from the listing. This is a very relevant step in UDI regulation, which requires data which has been made inactive to be permanently stored in a UDI database. In general master data management, the data element can be archived from the internal active database. The determination of which action applies usually depends on particular use case for which the data is intended, such as UDI regulation.

7. Purge

Generally speaking outdated information should be deleted from systems where it has been stored as part of the publication process. This should include the generation of a Purge List, which should be provided to the internal data owners and users. I some cases this may include the approval of the purge by the data owner.

The U.S. FDA UDI rule includes specific requirements regarding the information lifecycle management, which may supersede guidance found in this document. For additional information refer to the U.S. FDA GUDID User's Guide.

1.8. Data Governance

Data governance relates to an enterprise wide process which includes decision authority, policy and issue escalation. An enterprise wide Data Governance process should include data management, data quality, data policies and risk management and executive sponsorship. The process should ensure that certain data assets are formally recognized and managed throughout the organization.

Data Governance is a critical component of Master Data Management and especially important to the accuracy of the data requirements of a UDI regulation. Each manufacturer is responsible for submitting and maintaining their data in the UDI database.

Data Governance should include the decision rights and accountability of the key pillars:

- Executive: Internal sponsors of the Master Data Management process within an organization executive management.
- Legal / Legislative: Internal sponsors responsible for the representation of regulatory affairs as it relates to information management and publication in both internal and external systems and databases. This includes legal compliance, legislative and regulatory requirements. This is especially important with UDI regulation.
- Administrative: Internal function responsible for the maintenance of the Master Data. The function can be either centralized or decentralized.

Refer to the Roles and Responsibilities section of this document for more information in functional responsibilities.

1.9. Roles and Responsibilities

The Data Governance policies should include clear determination, documentation and enterprise wide education of the Roles and Responsibilities of each function across the information supply chain. This should include a determination of how data is managed within an organization and the roles associated with the process. Generally speaking, there are two overarching models, centralized or decentralized. Most commonly, the responsibilities are spread across an entire organization ranging from manufacturing, to product management to regulatory affairs. Which model applies to a particular organization depends on many factors, such as organizational structure, size and policies related to corporate versus division autonomy and perhaps even legal incorporation of the various divisions, which make up the organization.

There are many models for establishing and documenting Roles and Responsibilities. The first step should be to determine if your organization has a corporate philosophy or policy for assigning roles and responsibilities for information lifecycle management. If not, a basic place to start might be the RACI model.

- **R = Responsible** - owns the project, problem or task. The person responsible for doing the work to achieve the task
- **A =** to whom the R is **Accountable** - who must sign-off (approve) work before it is effective
- **C =** to be **Consulted** – has information and/or capability necessary to complete the work
- **I =** to be **Informed** – must be notified of results, need not be consulted

This simple yet effective model can be applied in any size company. In large organizations, which include divisions in various parts of the world the roles and responsibilities are usually managed in decentralized manner. Conversely, in a small organisation everyone involved in the information management supply chain may be located in a single location. The level of specificity depends on the granularity needed in order for the Master Data Management and Governance process to be effective and for it to meet its intended purpose. For the purpose of UDI regulation, the internal Regulatory Affairs function should be consulted as well.

2. GDSN Data Flow

This section is specific to the U.S. FDA GUDID as it is the first UDI database. This section will be updated as other regulators introduce UDI regulation.

Options for registering data in the FDA GUDID:

1. Manual data entry via the Web based tool. This refers to a web portal provided by the U.S. FDA to register data directly in their GUDI. The portal provides a means for the medical device manufacturer to enter and update their data manually directly in their database.

2. Bulk data registration direct from a manufacturer's internal application using the HL7 standard. This refers to a machine to machine automated method of registering data. It requires the use of the Standard Product Labelling standard from HL7. This provides the means for a manufacturer to register data directly from an internal application, such as an ERP, to the GUDID. The manufacturer must convert their internal data record into the HL7 SPL standard.
3. GDSN certified Data Pools can register data on behalf of the manufacturers using the HL7 Structured Product Labeling (SPL) standard. The manufacturer will need list their data pool as their data provider when they create their "Labeler" profile with the FDA. GS1 successfully tested this capability with 8 manufacturers with the support of 1Worldsync and GHX in 2012 during the FDA's user acceptance testing.

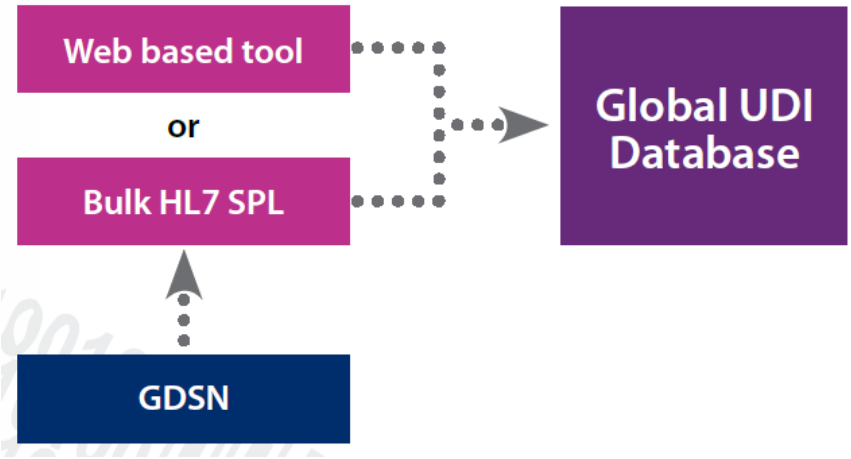

Illustration 2

The GDSN is an Internet-based, interconnected, network of interoperable data pools and a Global Registry, the GS1 Global Registry® that enables companies around the world to exchange accurate, standardised and synchronised supply chain data with their trading partners. The Global Data Synchronisation Network (GDSN) enables manufacturers, distributors and providers to share accurate product information electronically. In addition to receiving the initial product data, the customer can receive product update notifications automatically from the supplier.

The GDSN is an attractive option for manufacturers who also need to provide product master data to providers, GPOs and distributors since it allows them to provide the right data to the right party with a single connection, as illustrated below.

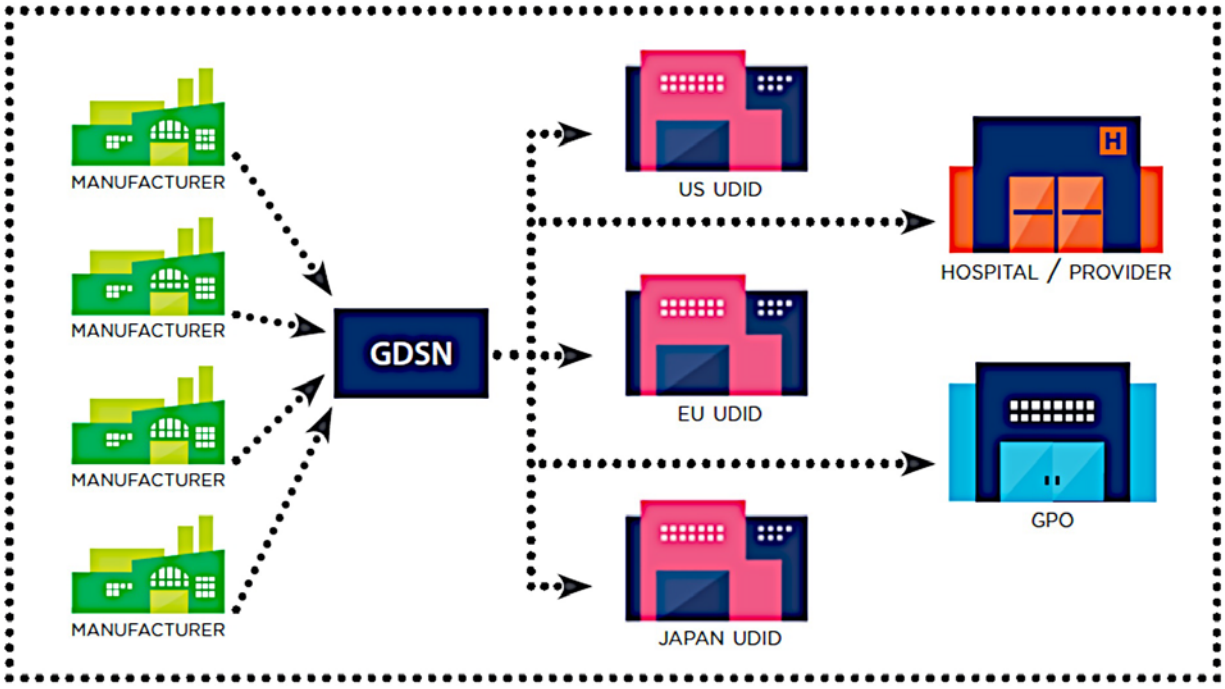

Illustration 3

Regulators are working together via the International Medical Device Regulators Forum (IMDRF) to align as much of their requirements as possible. However, each regulator will probably have a specific and distinct set of data requirements. This means that manufacturers will need to maintain separate data records for each UDI regulator's database. Additionally, they will need to establish separate connections, or methods, of registering their product data in the particular UDI database. The GDSN provides a means for any manufacturer of any size, to provide data to all UDI databases and their customers (hospitals, distributors, wholesalers, GPOs) simultaneously, with a single connection.

Below are the high-level steps of the data flow from the manufacturer to the GUDID when using a GDSN Data Pool.

1. The manufacturer prepares data required by the Global UDI Database
2. The manufacturer provides GUDID data to their GDSN Data Pool of choice
3. The GDSN Data Pool converts the data provided by the manufacturer to the HL7 SPL format (refer to the GUDID User Manual for information)
4. The GDSN Data Pool registers the manufacturer's product data using the HL7 SPL format in the GUDID
5. The GDSN Data Pool confirms the registration with the Manufacturer, once a confirmation from the GUDID is received by the GDSN Data Pool.

The GDSN provides a secure and easy way for manufacturers to register their product data with any UDI database, anywhere in the world, via a single connection. Refer to the GDSN website for a list of GDSN certified Data Pools http://www.gs1.org/gdsn

3. GUDID Data Requirements

The Device Identifier (DI) is the primary key in the UDI database and will be linked to other product data elements. Manufacturers will be responsible for submitting and maintaining their own data in the

database The U.S. FDA Global UDI Database (GUDID) will not contain the Production Identifiers, i.e. Expiration Date, Batch/Lot Number, Serial Number or others.

> *"The core elements are the minimum elements needed to identify a medical device through distribution and use. Regional or National UDID may contain additional elements; however, these additional elements should be kept to a minimum"* – International Medical Device Regulators Forum (IMDRF), UDI System for Medical Devices

The Global Unique Device Identification Database (GUDID) has a set of attributes for population of information about a medical device. These attributes are of various types (Boolean, Code List, Text, etc.) and if it is "Required" or "Not Required". The specifics of each attribute varies based upon the information requested by the attribute's definition and the type of device being described.

The table below provides a list of the GUDID attributes and their particulars as current at the time of the creation of this document as provided by the FDA GUDID Guidance documents. While every effort is made to keep this document up to date, the official list of attributes and particulars is the responsibility and jurisdiction of the FDA. A website link to the official list is provided in the reference section of this document. Users of this document are encouraged to review and become familiar with the official list of attributes and particulars as listed on the FDA's websites. The table uses the headers as defined below.

Header	Definition
Data Element	The name of the element being requested.
Description	Text defining the element.
Data Entry Notes	How the is entry to be accomplished. The primary focus of the guidance is primarily written with a web interface user in mind. For a machine to machine user, the notes will have different meaning and be described in the guidance later in this document.
Edit Rules After Grace Period	Once published on the FDA GUDID public facing website for the first time, the user will have a 7-day grace period within which changes can be made. This field states what editing can be accomplished after the grace period expires.
Required?	Is this data element required to be populated by the FDA? 0 in the first position signifies not required, 1 in the first position signifies required, * after 2 periods signifies multiple occurrences/repeatability, a nd a number after 2 periods signifies single occurrence/non-repeatability
Data Type & Length	The type of value for the element (Boolean, Text, Code List, etc) including how many characters are available for population.
Entry List of Values (LOV)	This is a list of values which can be provided for code list attributes
New DI Trigger?	Indicator signifying if a change to this data element would trigger a new Device Identifier to be created. In GS1 Standards, this indicates if a new GTIN should be created due to a change in the value for this element.
Public/ Private Status	Indicator signifying if this element will be posted on the FDA GUDID public facing website (PUBLIC) or for FDA consumption only (PRIVATE)

Document reference:

- The FDA term GS1 14-digit numeric value is equal to a GTIN.
- The FDA term "Primary DI" in GS-speak would be the primary device GTIN. For example a DI 101 is the Primary GTIN and DIs 201 and 301 would be the packaging levels

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.						
Device Information						
Device Identifier (DI) Information						
Issuing Agency	Organization accredited by FDA to operate a system for the issuance of UDIs.	Choose a value from the drop down.	Cannot edit, add, or delete after Grace Period.	1..1 Required	Alphanumeric, 30	GS1; HIBCC; ICCBBA
Primary DI Number	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest level of a medical device containing a full UDI.	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value	Cannot edit, add, or delete after Grace Period.	1..1 Required	Numeric or Alphanumeric, 6-23 characters	N/A
Device Count	Number of medical devices in the base package. For example, Base Package = Box of 100 gloves; Primary DI = 101; Device Count = 100.	Enter a numeric value.	Cannot edit, add, or delete after Grace Period.	1..1 Required	Numeric, 7	N/A

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Unit of Use DI Number	An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value If Device Count =1, cannot add Unit of Use DI Number.	Can edit after Grace Period if Device Count > 1.	0..* Required if device count is greater than one	Numeric or Alphanumeric, 6-23 characters	N/A
Labeler DUNS Number	Business number issued by Dun & Bradstreet (D&B) that matches the Labeler (Company) name on device label.	Choose appropriate DUNS Number from drop down.	Can edit after Grace Period.	1..1 Required	Numeric, 9	from DUNS
Company Name	Company name associated with the labeler DUNS Number entered in the DI Record. This name should match the company name on the device label.	*System populated.*	Can be edited through D&B only.	1..1 Required	Alphanumeric	N/A
Company Physical Address	Company physical address associated with the DUNS Number entered in the DI. This address should match the address on the device label.	*System populated.*	Can be edited through D&B only.	1..1 Required	Alphanumeric	N/A

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Brand Name	The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand name is the name that is typically registered with USPTO and have the ® and/or TM symbol.	Enter the name of the device. Only the ® and ™ symbols will be supported for the production release.	Cannot edit after Grace Period.	1..1 Required	Alphanumeric and symbols, 80	N/A
Version or Model Number	The version or model number found on the device label or accompanying packaging used to identify a category or design of a device. The version or model means all devices that have specifications, performance,	Enter an alphanumeric value.	Cannot edit after Grace Period.	1..1 Required	Alphanumeric and symbols, 40	N/A

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
	size, and composition, within limits set by labeler.					
Catalog Number	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.	Enter an alphanumeric value. No symbols are accepted.	Can edit, add, or delete after Grace Period.	0..1 Not Required	Alphanumeric and symbols, 40	N/A
Device Description (max 2000 characters)	Additional relevant information about the device that is not already captured as a distinct GUDID data attribute.	Enter device description. Only the ® and ™ symbols will be supported for the production release	Can edit, add, or delete after Grace Period.	0..1 Not Required	Alphanumeric and symbols, 2000	N/A
Commercial Distribution						
DI Record Publish Date (mm/dd/yyyy)	Indicates the date the DI Record gets published and is available via Public Search.	Choose date from calendar or manually enter in format (mm/dd/yyyy). Cannot edit during or after Grace Period.	Cannot edit, add, or delete after Published.	1..1 Required	Numeric date format, 10	N/A
Commercial Distribution End Date (mm/dd/yyyy)	Indicates the date the device is no longer held or offered for sale. See 21 CFR 807.3(b) for exceptions. The device may or may not still be available for purchase in the	Choose date from calendar or manually enter in format (mm/dd/yyyy).	Can edit, add, or delete after Grace Period.	0..1 Not Required	Numeric date format, 10	N/A

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
	marketplace.					
Commercial Distribution Status	Indicates whether the device is in commercial distribution as defined under 21 CFR 807.3(b).	*System populated.*	N/A	0..1 Required if record is published	N/A	In Commercial Distribution; Not in Commercial Distribution
Alternative or Additional Identifiers						
Direct Marking (DM)						
Device Subject to Direct Marking (DM), but Exempt	The device is exempt from Direct Marking requirements under 21 CFR 801.45.	Select checkbox if appropriate.	Can add or delete after Grace Period.	0..1 Not Required	Boolean	N/A
DM DI Different from Primary DI	Indicates that the DM DI Number is different than the Primary DI Number.	Select checkbox if appropriate.	Can add or delete after Grace Period.	0..1 Not Required	Boolean	N/A
DM DI Number	An identifier that is marked directly on the medical device and is different than the Primary DI Number; only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45.	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value	Can edit, add, or delete after Grace Period.	0..* Required only if check box for 'DM DI Different from Primary DI'	Numeric or Alphanumeric, 6-23 characters	N/A
Secondary DI						
Secondary DI Issuing Agency	Name of Secondary DI Issuing agency.	Choose from drop down.	Cannot edit, add or delete after Grace Period	1..* Required if there is a Secondary DI Number	Alphanumeric, 30	GS1; HIBCC; ICCBBA; NHRIC

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Secondary DI Number	An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI.	GS1- 14- digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value NHRIC- 10-digit numeric value.	Cannot edit, add or delete after Grace Period	1..* Required if there is a Secondary DI Number	Numeric or Alphanumeric, 6-23 characters	N/A
Package DI	Can add Package Configuration after Grace Period, but cannot delete or edit Package Configurations entered prior to the end of the Grace Period.					
Package DI Number	A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers). For example: 4 glove boxes in a Carton -- Package DI =201 (the UDI on the Carton) 5 Cartons in a Case -- Package DI=301 (the UDI on the Case) contains a 5 cartons (with DI 201) with 4 glove boxes in a carton 10 glove boxes in a Carton -- Package DI=202 (the UDI on the Carton).	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value	Can add after Grace Period, but cannot delete.	0..* Not Required Required if Package Configuration is entered	Alphanumeric, 6-23 depending on Issuing Agency	N/A

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Quantity per Package	The number of packages with a unique primary DI within a given packaging configuration. For example: Package configuration Carton with Package DI=201 contains 4 boxes of the base package DI=101, the quantity per package is 4; Package configuration Case with Package DI=301 contains 5 cartons of Package DI=201, the quantity per package is 5. Package configuration Carton with Package DI=202 contains 10 boxes of the base package DI=101; the quantity per package is 10.	The quantity of a package configuration needs to be greater than 1.	Can add with new package configuration after Grace Period, but cannot delete	0..* Required if Package Configuration is entered	Numeric, 9	N/A

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Contains DI Package	The primary DI for the base package or any lower level package configuration contained within a given package configuration. For example: Package DI=201 and Package DI=202 contain the base package Case with primary DI=101; Package DI=301 contains lower level package configuration of a Carton with Package DI=201.	Choose a value from the drop down.	Can add with new package configuration after Grace Period, but cannot delete	0..* Required if Package Configuration is entered	Alphanumeric, 6-23 depending on Issuing Agency	N/A
Package Type	Text to describe the outer packaging of the product and enables users to understand higher level packaging configurations.	Free text.	Can add with new package configuration after Grace Period, but cannot delete	0..1 Not Required	Alphanumeric, 20	N/A
Package Discontinue Date	Indicates the date this particular package configuration is discontinued by the labeler.	Choose date from calendar or manually enter in format (mm/dd/yyyy).	Can add with new package configuration after Grace Period, but cannot delete.	0..* Required if both Package Configuration and Commercial Distribution End Date are entered	Numeric date format, 10	N/A

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Package Status	Indicates whether the package configuration is available or discontinued.	System populated.	N/A	0..* Required if Published	Alphanumeric	In Commercial Distribution; Not in Commercial Distribution
Support Contact						
Support Contact Phone	Phone number for the support contact.	Enter 10 digit North American number. For international numbers, start with "+" Does not require the use of () or -, but can enter these symbols.	Can edit, add, or delete after Grace Period.	1..* Required if support contact information is entered	Numeric, 20 (10)	N/A
Support Contact Email	Email for the support contact.	Enter alphanumeric email address in format ---@--.--	Can edit, add, or delete after Grace Period.	1..* Required if support contact information is entered	Alphanumeric, 100	N/A
Device Status						
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3.	Check box if appropriate.	Can add or delete after Grace Period.	0..1 Not Required	Boolean	N/A
Kit	Indicates that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a	Check box if DI record is for the kit itself. Do not check if the product is part of a kit.	Cannot add or delete after Grace Period.	0..1 Not Required	Boolean	N/A

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
	collection of products, including medical devices, that are packaged together to achieve a common intended use and is being distributed as a medical device.					
Combination Product	Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case.	Check box if DI record is for the combination product itself. Do not check if the product is a constituent part of a combination product.	Cannot add or delete after Grace Period.	0..1 Not Required	Boolean	N/A

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Premarket						
Device Exempt from Premarket Submission	Device is exempt from FDA Premarket regulations; or a preamendment device.	Check box if appropriate.	Cannot add or delete after Grace Period.	0..1 Not Required Required if device is exempt from premarket submission	NO	N/A
FDA Premarket Submission Number	Number associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA.	Enter all valid FDA Premarket Submission Numbers.	Can add after Grace Period, but cannot delete or edit.	1..* Required Not required if Device Exempt from Premarket Submission is selected Not required for Kits Required for HCT/Ps	Alphanumeric, 8	N/A
Supplement Number	Number assigned by FDA to a supplemental application for approval of a change in a medical device with an approved PMA, HDE, or PDP.	Enter all valid Supplement Numbers. Do not enter any alpha characters.	Can add after Grace Period, but cannot delete or edit.	0..1 Not Required unless Device contains Supplement. Not required if Device Exempt from Premarket Submission is selected. Not required for Kits.	Numeric, 4	N/A
FDA Product Code						
Product Code	Classification for pre-market devices issued by the FDA; three letter code.	Enter all applicable Product Codes.	Can edit, add, or delete after Grace Period.	0..* Required for all medical devices except for Kits or IVDs (BL premarket submission number)	Alpha, 3	FDA Product Code list
Product Code Name	Name associated with the three-letter Product Code.	*System populated*	N/A	1..1 Required with Product Code	Alphanumeric, 360	FDA Product Code list

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
FDA Listing						
FDA Listing Number	Number assigned by FDA during Registration and Listing to all devices in commercial distribution, regardless of pre-market authorization requirements per 21 CFR 807.28(f).	Enter all applicable Listing Numbers	Can add after Grace Period, but cannot delete or edit.	0..* Required for all medical devices except for HCT/Ps, Kits, and IVDs (BL premarket submission number).	Alphanumeric, 7	N/A
GMDN						
Code	Unique numerical five-digit code used to generically identify medical devices and related health care products.	Enter all applicable GMDN Preferred Term Codes.	Can edit, add, or delete after Grace Period.	1..* Required	Numeric, 5	GMDN list
Name	Name associated with the GMDN Preferred Term Code.	*System populated based on GMDN Preferred Term Code.*	N/A	1..1 Required	Alphanumeric	GMDN list
Definition	Description associated with the GMDN Preferred Term Code.	*System populated based on GMDN Preferred Term Code.*	N/A	1..1 Required	Alphanumeric	GMDN list
Device Characteristics						
For Single-Use	Indicates that the device is intended for one use or on a single patient during a single procedure.	Choose a value from the drop down.	Cannot edit after Grace Period.	1..1 Required	N/A	Yes/No
Production Identifier(s) on Label						

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Lot or Batch Number	Flag to indicate the device is managed by lot or batch number. This number can be found on the device label or packaging. Lot or Batch means one finished device or more that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.	Choose a value from the drop down.	Can edit after Grace Period.	1..1 Required	Boolean	Yes/No
Manufacturing Date	Flag to indicate the device is managed by date of manufacture; the date a specific device was manufactured.	Choose a value from the drop down.	Can edit after Grace Period.	1..1 Required	Boolean	Yes/No
Serial Number	Flag to indicate the device is managed by serial number. This number can be found on the device label or packaging. The serial number is	Choose a value from the drop down.	Can edit after Grace Period.	1..1 Required	Boolean	Yes/No

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
	assigned by the labeler and should be specific to each device.					
Expiration Date	Flag to indicate the device is managed by expiration date; the date by which the label of a device states that the device must or should be used.	Choose a value from the drop down.	Can edit after Grace Period.	1..1 Required	Boolean	Yes/No
Latex Information						
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. Choosing yes indicates that the device label or packaging contains one of the following statements: (1) "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions", (2) This Product Contains Dry Natural Rubber", (3) Caution: The Packaging of This Product	Choose a value from the drop down.	Cannot edit after Grace Period.	1..1 Required	Boolean	Yes/No

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
	Contains Natural Rubber Latex Which May Cause Allergic Reactions" or (4) "The Packaging of This Product Contains Dry Natural Rubber".					
Device labeled as "Not made with natural rubber latex"	Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container. Only applicable to devices not subject to the requirements under 21 CFR 801.437.	Check box if appropriate. Only applicable if the response to "Device required to be labeled as containing natural rubber latex or dry natural rubber" was "No".	If selected "Yes" to "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)", cannot add or delete check to this field. If selected "NO" to "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)", can add or delete check to this field.	0..1 Not Required	Boolean	N/A
Prescription Status						
Prescription Use (Rx)	Indicates that the device requires a prescription to use.	Select check box if appropriate	Can add or delete after Grace Period.	0..1 Not Required	Boolean	N/A
Over the Counter (OTC)	Indicates that the device does not require a prescription to	Select check box if appropriate	Can add or delete after Grace Period.	0..1 Not Required	Boolean	N/A

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
	use and can be purchased over the counter (OTC).					
MRI Safety Status						
Is the device labeled for MRI Safety?	Indicates that sufficient testing has been conducted to characterize the behavior of the device in the MR environment. See ASTM F2503-13.	Check box if appropriate.	Can add check to checkbox after Grace Period, but cannot delete a check from the checkbox.	0..1 Not Required	Boolean	N/A
MRI Safety Status	Indicates the MR safety status of the device. The three drop down values are: MR Safe, MR Conditional, and MR Unsafe. Please see the ASTM F2503-13 standard for more information on these three values.	Must select one value from drop-down if selected check box for "Has the device been evaluated for MRI Safety?"	Can add MRI Safety Status after Grace Period only if the field 'Has the device been evaluated for MRI Safety?' was previously unchecked. Cannot edit after Grace Period if 'Has the device been evaluated for MRI Safety?' was previously checked.	1..* Required if selected check box for "Is the device labeled for MRI Safety?"	N/A	MR Safe; MR Unsafe; MR Conditional

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Clinically Relevant Size						
Size Type	Dimension type for the clinically relevant measurement of the medical device.	Choose a value from the drop down.	Can add after Grace Period, but cannot delete or edit.	0..* Not Required Required if Size is provided	N/A	Circumference; Depth; Device Size Text, specify; French Catheter Gauge ; Greatest Diameter; Height; Length; Lumen Diameter; Needle Gauge; Second Greatest Diameter; Third Greatest Diameter; Total Volume; Width
Size Value	Numeric value for the clinically relevant size measurement of the medical device.	Enter numeric value	Can add after Grace Period, but cannot delete or edit.	1..* Required if Size is provided	Numeric, 40	N/A
Size Unit of Measure	The unit of measure associated with each clinically relevant size.	Choose a value from the drop down.	Can add after Grace Period, but cannot delete or edit.	1..* Required if Size is provided	Numeric, 20	For lengths: Centimeter; Cubic Inch; Decimeter; Feet; Femtometer; French; Inch; Kilometer; Meter; Microliter; Micrometer; Millimeter; Nanometer; Picometer; Pint; Square Centimeter; Square Feet; Square Inch; Square Meter; Square Millimeter; Ton; Yard For 'Total Volume': Centiliter ; Cup; Deciliter; Femtoliter; Fluid Ounce; Gallon; Kiloliter; Liter; Micrograms per Total Volume; Milligrams per Total Volume; Milliliter; Nanoliter; Picoliter; Quart; Units per liter

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Size Type Text	Additional undefined device size not represented in the GUDID clinically relevant size list.	Enter size type text in addition to units.	Can add after Grace Period, but cannot delete or edit.	0..* Not Required	Alphanumeric (including symbols), 200	N/A
Storage and Handling						
Storage and Handling Type	Indicates storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure.	Choose a value from the drop down.	Can edit, add, or delete after Grace Period.	0..* Not Required Required if Storage and Handling is provided	N/A	Handling Environment Atmospheric Pressure; Handling Environment Humidity; Handling Environment Temperature; Special Storage Conditions; Storage Environment Atmospheric Pressure; Storage Environment Humidity; Storage Environment Temperature
Low Value	Indicates the low value for storage and handling requirements.	Must enter a Low Value and/or High Value if entering a Storage and Handling Type	Can edit, add, or delete after Grace Period.	0..* A Low Value and/or a High Value is required if Storage and Handling is provided.	Numeric, 6	N/A
High Value	Indicates the high value for storage and handling requirements.	Must enter a Low Value and/or High Value if entering a Storage and Handling Type	Can edit, add, or delete after Grace Period.	0..* A Low Value and/or a High Value is required if Storage and Handling is provided.	Numeric, 6	N/A
Unit of Measure	The unit of measure associated with the storage and handling conditions. The unit of measure must conform to UCUM standards.	Choose a value from the drop down.	Can edit, add, or delete after Grace Period.	0..* Required if Storage and Handling is provided	N/A	Degrees Celsius; Degrees Fahrenheit; Degrees Kelvin; Kilo Pascal; Percent (%) Relative Humidity

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)
Special Storage Conditions	Indicates any special storage requirements for the device.	Can enter alphanumeric with symbols	Can edit, add, or delete after Grace Period.	0..* Not Required Required if Special Storage Condition Text selected	Alphanumeric, 200	Free Text
Sterilization Method						
Device Packaged as Sterile	Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.	Choose a value from the drop down.	Cannot edit after Grace Period.	1..1 Required	Boolean	Yes/No
Requires Sterilization Prior to Use	Indicates that the device requires sterilization prior to use.	Choose a value from the drop down.	Cannot edit after Grace Period.	1..1 Required	Boolean	Yes/No
Sterilization Method	Indicates the method(s) of sterilization that can be used for this device.	Choose a value from the drop down.	Can edit, add or delete after Grace Period only if 'Yes' was selected for 'Requires Sterilization Prior to Use' before Grace Period. Cannot add Sterilization Methods after Grace Period if 'No' was selected for 'Requires Sterilization Prior to Use' before Grace Period.	1..* Required if 'Requires Sterilization Prior to Use' is marked 'Yes'	N/A	Chlorine Dioxide; Dry Heat; Ethylene Oxide; High Intensity Light or Pulse Light; Hydrogen Peroxide; Microwave Radiation; Moist Heat or Steam; Ozone; Peracetic Acid; Radiation; Sound Waves; Ultraviolet Light

4. GS1 GDSN to FDA GUDID Mapping

Population of the FDA GUDID through the use of a GS1 GDSN message and a GDSN Certified Data Pool as a Third Party requires an understanding of the GDSN and its attributes. While many of the FDA GUDID attributes can be mapped one to one with a GS1 GDSN equivalent, there are others that do not map (and are logically populated) or map via more than one GDSN attribute.

The first table below provides a mapping between the FDA GUDID attribute list and the corresponding GS1 GDSN Attribute(s). The attributes listed in the table use the name assigned in the GDSN standards. Each user of this document should consult with their GDSN Certified Data Pool for the exact naming convention and message formatting applicable to the contract between the user and the Data Pool.

The second table below provides a mapping between the FDA GUDID code values and the corresponding GS1 GDSN code values. The values listed in the table use the name assigned in the GDSN standards. Each user of this document should consult with their GDSN Certified Data Pool for the exact naming convention and message formatting applicable to the contract between the user and the Data Pool.

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
Device Information				
Device Identifier (DI) Information				
Issuing Agency	Data Pool to default on outbound message			LOGICAL POPULATION- On the outbound GUDID Message by the Data Pool. Will use the value "GS1" in all GDSN instances.
Primary DI Number	globalTradeItemNumber	Numeric (14 Characters)	EAN.UCC numbering structures will be used for the identification of trade items. All of them will be considered as 14-digit Global Trade Item Number (GTIN). Must be present to enable data to be presented to trade item catalogue. Must be submitted by the owner of the data (who may be the original manufacturer, the importer, the broker or the agent of the original manufacturer). This field is mandatory within the Global Data Synchronization work process.	This GTIN should be the lowest level fors the hierarchy.
Device Count	netContent +UoM	Numeric + Code List	The amount of the trade item contained by a package, usually as claimed on the label. For example, Water 750ml - net content = "750 MLT" ; 20 count pack of diapers, net content = "20 ea.". In case of multi-pack,	

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
			indicates the net content of the total trade item. For fixed value trade items use the value claimed on the package, to avoid variable fill rate issue that arises with some trade item which are sold by volume or weight, and whose actual content may vary slightly from batch to batch. In case of variable quantity trade items, indicates the average quantity.	
Unit of Use DI Number	fDAUnitOfUseGTIN	GTIN	GTIN of a unit of use, as defined by the FDA. This is a lower level unit, which is contained in the Trade Item.	AVP- fDAUnitOfUseGTIN
Labeler DUNS Number	additionalPartyIdentificationType	Code List	Identification of a party by use of a code other than the Global Location Number.	This pair of attributes will be provided as additional party identification for the Brand Owner GLN
	additionalPartyIdentificationValue	Text	A party identifier that is in addition to the GLN.	
Company Name				FDA will populate based on the DUNS and D&B
Company Physical Address				FDA will populate based on the DUNS and D&B
Brand Name	brandName	Text (1 to 35 characters)	The recognisable name used by a brand owner to uniquely identify a line of trade item or services. This is recognizable by the consumer.	
Version or Model Number	additionalTradeItemIdentificationType	Code List	Type of the identification system that is being used as an alternative to the Global Trade Item Number.	Use code value of MODEL_NUMBER
	additionalTradeItemIdentificationValue	Text	Alternative means to the Global Trade Item Number to identify a trade item.	
Catalog Number	additionalTradeItemIdentificationType	Code List	Type of the identification system that is being used as an alternative to the Global Trade Item Number.	Use code value of SUPPLIER_ASSIGNED
	additionalTradeItemIdentificationValue	Text	Alternative means to the Global Trade Item Number to identify a trade item.	

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
Device Description (max 2000 characters)	additionalTradeItemDescription	Text (1 to 350 characters)	Additional variants necessary to communicate to the industry to help define the product. Multiple variants can be established for each GTIN. This is a repeatable field, e.g. Style, Colour, and Fragrance. The schema uses common library component as shown in the GDD Max Size field. For the business requirements for item, please use the specific definition of this data type and field, 1-350.	CONCATENATION-tradeItemDescription and additionalTradeItemDescription
	tradeItemDescription	Text (1 to 178 characters)	An understandable and useable description of a trade item using brand and other descriptors.This attribute is filled with as little abbreviation as possible while keeping to a reasonable length. Free form text field, this data element is repeatable	CONCATENATION-tradeItemDescription and additionalTradeItemDescription
Commercial Distribution				
DI Record Publish Date (mm/dd/yyyy)	effectiveDate	Date (CCYY-MM-DDTHH:MM:SS)	The date on which the information contents of the master data version are valid. Valid = correct or true. This effective date can be used for initial trade item offering, or to mark a change in the in-formation related to an existing trade item. This date would mark when these changes take effect.	
Commercial Distribution End Date (mm/dd/yyyy)	lastShipDate	Date Time (CCYY-MM-DDTHH:MM:SS)	Indicates the latest date that the trade item can be shipped. This is independent of any specific ship-from location.	
Commercial Distribution Status				FDA will populate based on the publication date (effectiveDate) and the lastShipDate.
Alternative or Additional Identifiers				

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
Direct Marking (DM)				
Device Subject to Direct Marking (DM), but Exempt	isTradeItemExemptFromDirectPartMarking	Boolean	Indicator signifying the trade item is exempt from direct identification marking according to regulation or regulatory filings within the target market.	AVP- isTradeItemExemptFromDirectPartMarking
DM DI Different from Primary DI	Data Pool to default on outbound message	Boolean		LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of a value of DIRECT_PART_MARKING in additionalTradeItemIdentification)
DM DI Number	directPartMarking	Text	This is a number or marking placed directly on the medical device.	AVP- directPartMarking
Secondary DI				
Secondary DI Issuing Agency	additionalTradeItemIdentificationType	Code List	Type of the identification system that is being used as an alternative to the Global Trade Item Number.	
Secondary DI Number	additionalTradeItemIdentificationValue	Code List	Alternative means to the Global Trade Item Number to identify a trade item.	
Package DI	Can add Package Configuration after Grace Period, but cannot delete or edit Package Configurations entered prior to the end of the Grace Period.			
Package DI Number	globalTradeItemNumber (use hierarchy to obtain parent-child information)	Numeric (14 Characters)	EAN.UCC numbering structures will be used for the identification of trade items. All of them will be considered as 14-digit Global Trade Item Number (GTIN). Must be present to enable data to be presented to trade item catalogue. Must be submitted by the owner of the data (who may be the original manufacturer, the importer, the broker or the agent of the original manufacturer). This field is mandatory within the Global Data Synchronization work process.	FDA GUDID contains the lowest level of the GDSN hierarchy as its primary. Higher levels of packaging are only referenced as package levels. See additional guidance below for more details.
Quantity per Package	totalQuantityOfNextLowerLevelTradeItem	Numeric	This represents the Total quantity of next lower level trade items that this trade	

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
			item contains.	
Contains DI Package	childGTIN	Numeric (14 Characters)	A particular Global trade item Number, a numerical value used to uniquely identify a trade item. A trade item is any trade item (trade item or service) upon which there is a need to retrieve pre-defined information and that may be planned, priced, ordered, delivered and or invoiced at any point in any supply chain. In this context, the GTIN for the current item which is a child item of another item.	
Package Type	packagingTypeCode	Text (1-3 characters)	The code identifying the type of package used as a container of the trade item.	
	packagingTypeDescription	Text (1-70 characters)	System generated text description of the type of packaging used for the trade item.	LOGICAL POPULATION- (Logical Population by Data Pools based on the Packaging Type Code value populated.) Only the description is provided to the GUDID
Package Discontinue Date	discontinuedDate	DateTime	Communicate the date on which the trade item is no longer to be manufactured. Allows the reuse of the GTIN after 48 months with the explicit exception of Apparel, being 30 months and the implicit exception for specialty products (e.g., steel beams).	
Package Status				FDA will populate based on the publication date (effectiveDate) and the lastShipDate.
Support Contact				
	contactType	Code List	The general category of the contact party for a trade item for example Purchasing.	Value populated for the contact information is the LICENSEE_REGISTRAR or CUSTOMER_SUPPORT
Support Contact Phone	communicationChannelCode	Code List	Means used to communicate with another party.	Value populated for the support contact phone number is TELEPHONE

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
	communicationNumber	Text (1-70 characters)	Number assigned to a specific means of communication.	
Support Contact Email	communicationChannelCode	Code List	Means used to communicate with another party.	Value populated for the support contact email is EMAIL
	communicationNumber	Text (1-70 characters)	Number assigned to a specific means of communication.	
Device Status				
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	doesTradeItemContainHumanTissue	Boolean	The trade item has, as a component or ingredient, human tissue. The amount of tissue is not limited to a certain amount, any amount will cause a flag of TRUE.	AVP- doesTradeItemContainHumanTissue
Kit	groupedProduct	Code List	Code representing if the trade item is considered by the manufacturer to be more than a single item, such as a kit, combination item.	AVP- groupedProduct (KIT)
Combination Product				AVP- groupedProduct (COMBINATION)
Premarket				
Device Exempt from Premarket Submission	exemptFromFDAPreMarketAuthorization	Boolean	Device is exempt from FDA Premarket regulations. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined	AVP- exemptFromFDAPreMarketAuthorization External Code managed by FDA.

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
			that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing clearance. Please note that some Class III preamendment devices may require a Class III 510(k). See "Historical Background2" for additional information.	
FDA Premarket Submission Number	additionalClassificationCategoryAgency	Code List	Text name of the additional external classification agency whose schema is being provided in addition to the Global EAN.UCC schema. Required if additional classification schema fields are populated.	Use code of FDA_510K_PREMARKET_NOTIFICATION, when available in GDSN. AVP- fDA510KPremarketAuthorization External Code managed by FDA.
	additionalClassificationCategoryCode	Text (1-15 characters)	Category code based on alternate classification schema chosen in addition to EAN/UCC classification schema.	
Supplement Number	fDASupplementNumber	Code List	Number associated with the regulatory decision regarding the applicant's legal right to market a medical device (PMA Supplement). After FDA has approved a PMA, an applicant must submit a PMA supplement for review and approval by FDA before making any change affecting the safety or effectiveness of the device unless FDA has advised that an alternate type of submission is permitted for a particular change. All changes must meet the requirements of the Quality System regulation (Good Manufacturing Practices) under 21 CFR Part 820 including the design control requirement under §820.30. Changes for which an applicant	AVP- fDASupplementNumber External Code managed by FDA. (Should be multiple occurrence)

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
			must submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device: new indication for use of the device; labeling changes; the use of a different facility or establishment to manufacture, process, sterilize, or package the device; changes in manufacturing facilities, methods, or quality control procedures; changes in sterilization procedures; changes in packaging; changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device; and extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by FDA. [If the protocol has been previously approved by FDA, a supplement is not submitted but the change must be reported to FDA in the post approval periodic reports as described in the §814.39(b).]	
FDA Product Code				
Product Code	additionalClassificationCategoryAgency	Code List	Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k). This allows FDA to determine whether the device is equivalent to a device already placed into one of the three	Use code 43

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
			classification categories. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.	
	additionalClassificationCategoryCode	Text (1-15 characters)	Category code based on alternate classification schema chosen in addition to EAN/UCC classification schema.	Code value managed by FDA.
Product Code Name				FDA will populate based on the FDA Product Code
FDA Listing				
FDA Listing Number	additionalTradeItemIdentificationType	Code List	Type of the identification system that is being used as an alternative to the Global Trade Item Number.	
	additionalTradeItemIdentificationValue	Code List	Alternative means to the Global Trade Item Number to identify a trade item.	
GMDN				

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
Code	additionalClassificationAgency	Code List	Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k). This allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.	Use code 35
	additionalClassificationCode	Text (1-15 characters)	Category code based on alternate classification schema chosen in addition to EAN/UCC classification schema.	Code value managed by GMDN. Only the GMDN Code is provided to the GUDID
Name	additionalClassificationCategoryDescription	Text (1-70 characters)	In the additional classification system, the description of the category.	FDA will populate based on the FDA Product Code. Can be provided via GDSN for supply chain purposes, but will not be populated to the GUDID from GDSN.
Definition				FDA will populate based on the FDA Product Code
Device Characteristics				

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
For Single-Use	manufacturerDeclaredReusabilityType	Code List	Determines if the product is intended for single or multiple uses; including the number of validated cycles and the number of times a product can be used according to the manufacturer specifications. It is suggested that medical providers consult the device manufacturer's Instruction For Use (IFU) for full reusability instructions.	LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of a value of SINGLE_USE in manufacturerDeclaredReusabilityType, all other values equate to a FALSE value)
Production Identifier(s) on Label				
Lot or Batch Number	hasBatchNumber	Boolean	Indication whether the base trade item is batch or lot number requested by law, not batch or lot number requested by law but batch or lot number allocated, or not batch or lot number allocated. A batch or lot number is a manufacturer assigned code used to identify a trade item's trade item on batch or lot. Differs from Serial Number which is a manufacturer assigned code during the trade item on cycle to identify a unique trade item.	
Manufacturing Date	isPackageMarkedWithManufactureDate	Boolean	Is the package marked with the date upon which the trade item was manufactured.	AVP- isPackageMarkedWithManufactureDate

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
Serial Number	serialNumberLocationCode	Text (1-35 characters)	The location on the item or packaging of a serial number. A serial number is a code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime for example a Microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569.	LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of any value except NOT_MARKED or UNKNOWN in serialNumberLocaitonCode)
Expiration Date	packagingMarkedExpirationDateType	Code List	Indicates the type of expiration date marked on the packaging.	LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of either values of BEST_BEFORE_DATE or EXPIRY_DATE in packagingMarkedExpirationDateType (changing to tradeItemDateOnPackagingType (coming in GDSN Major Release 3.x in 2016) other values or when no value is provided would equate to a value of FALSE)
Latex Information				
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	doesTradeItemContainLatex	Non-Binary Code List	An indication that a trade item is made from or contains latex which refers generically to a stable dispersion (emulsion) of polymer microparticles in an aqueous medium.	This definition is currently listed on the Global Data Dictionary, but will be changed in a future GDSN release to the definition and wording at this link. Please use this new wording when populating the attribute.
Device labeled as "Not made with natural rubber latex"	packageMarksFreeFrom	Code List	Indication of the food ingredients that the package is marked free from.	Use value of FREE_FROM_LATEX
Prescription Status				
Prescription Use (Rx)	ConsumerSalesCondition	Text (1-35 characters)	A code depicting restrictions imposed on the Trade Item regarding how it can be sold to the consumer for example Prescription Required.	Use value of PRESCRIPTION_REQUIRED
Over the Counter (OTC)				Use value of OTC
MRI Safety Status				

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
Is the device labeled for MRI Safety?	Data Pool to default on outbound message			LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of any value other than UNKNOWN in mRICompatibility)
MRI Safety Status	mRICompatibility	Code List	This is an identification of the compatibility of a trade item for use in the presence of a Magnetic Resonance Imaging (MRI) system.	
Clinically Relevant Size				
Size Type	clinicalSizeType	Code List	The qualifier to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user. For example "needle gauge" for a 16 gauge needle, or "volume" for a 200 cc syringe.	AVP- clinicalSizeType
Size Value	clinicalSizeValue + UoM	Numeric + Code List	The value to denote the dimensional size, which is clinically relevant for the use of the trade item by the clinical user. For example 16 gauge for a needle, or 200 cc for a syringe. Carries a UoM from the Recommendation 20 code list.	AVP- clinicalSizeValue and clinicalSizeValueUoM
Size Unit of Measure				
Size Type Text	clinicalSizeText	Text (1 to 200 characters)	When the clinicalSizeType is coded as "other", this is the text used to denote the dimensional size, which is clinically relevant for the use of the trade item by the clinical user.	AVP- clinicalSizeText
Storage and Handling				
Storage and Handling Type	storageEnvironmentAtmosphericPressureMaximum + UoM	Numeric + Code List	The maximum atmospheric pressure in which the item should be stored to remain usable. This value is the value above which the trade item should not be subjected.	AVP- storageEnvironmentAtmosphericPressureMaximum
	storageEnvironmentAtmosphericPressureMinimum + UoM	Numeric + Code List	The minimum atmospheric pressure in which the item should be stored to remain usable. This value is the value below which the trade item should not be subjected.	AVP- storageEnvironmentAtmosphericPressureMinimum

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
High Value	storageEnvironmentAtmosphericPressureMaximum + UoM	Numeric + Code List	The maximum atmospheric pressure in which the item should be stored to remain usable. This value is the value above which the trade item should not be subjected.	AVP-storageEnvironmentAtmosphericPressureMaximum
Unit of Measure				
Low Value	storageEnvironmentAtmosphericPressureMinimum + UoM	Numeric + Code List	The minimum atmospheric pressure in which the item should be stored to remain usable. This value is the value below which the trade item should not be subjected.	AVP-storageEnvironmentAtmosphericPressureMinimum
Unit of Measure				
Storage and Handling Type	storageHandlingHumidityMaximum + UoM	Numeric + Code List	The maximum humidity in percentages that the goods should be stored in.	GUDID Code for Storage Type- Storage environment humidity
	storageHandlingHumidityMinimum + UoM	Numeric + Code List	The minimum humidity in percentages that the goods should be stored in.	GUDID Code for Storage Type- Storage environment humidity
High Value	storageHandlingHumidityMaximum + UoM	Numeric + Code List	The maximum humidity in percentages that the goods should be stored in.	GUDID Code for Storage Type- Storage environment humidity
Unit of Measure				
Low Value	storageHandlingHumidityMinimum + UoM	Numeric + Code List	The minimum humidity in percentages that the goods should be stored in.	GUDID Code for Storage Type- Storage environment humidity
Unit of Measure				
Storage and Handling Type	storageHandlingTemperatureMaximum + UoM	Numeric + Code List	The maximum temperature at which the trade item can be stored. This uses a measurement consisting of a unit of measure and a value.	GUDID Code for Storage Type- Storage environment temperature
	storageHandlingTemperatureMinimum + UoM	Numeric + Code List	The minimum temperature at which the trade item can be stored. This uses a measurement consisting of a unit of measure and a value.	GUDID Code for Storage Type- Storage environment temperature
High Value	storageHandlingTemperatureMaximum + UoM	Numeric + Code List	The maximum temperature at which the trade item can be stored. This uses a measurement consisting of a unit of measure and a value.	GUDID Code for Storage Type- Storage environment temperature
Unit of Measure				

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
Low Value	storageHandlingTemperatureMinimum + UoM	Numeric + Code List	The minimum temperature at which the trade item can be stored. This uses a measurement consisting of a unit of measure and a value.	GUDID Code for Storage Type- Storage environment temperature
Unit of Measure				
Storage and Handling Type	transportationEnvironmentAtmosphericPressureMaximum + UoM	Numeric + Code List	The maximum atmospheric pressure in which the item should be transported to remain usable. This value is the value above which the trade item should not be subjected.	AVP-transportationEnvironmentAtmosphericPressureMaximum
	transportationEnvironmentAtmosphericPressureMinimum + UoM	Numeric + Code List	The minimum atmospheric pressure in which the item should be transported to remain usable. This value is the value below which the trade item should not be subjected.	AVP-transportationEnvironmentAtmosphericPressureMinimum
High Value	transportationEnvironmentAtmosphericPressureMaximum + UoM	Numeric + Code List	The maximum atmospheric pressure in which the item should be transported to remain usable. This value is the value above which the trade item should not be subjected.	AVP-transportationEnvironmentAtmosphericPressureMaximum
Unit of Measure				
Low Value	transportationEnvironmentAtmosphericPressureMinimum + UoM	Numeric + Code List	The minimum atmospheric pressure in which the item should be transported to remain usable. This value is the value below which the trade item should not be subjected.	AVP-transportationEnvironmentAtmosphericPressureMinimum
Unit of Measure				
Storage and Handling Type	transportationHumidityMaximum + UoM	Numeric + Code List	The maximum humidity in percentages in which the trade items should be transported.	AVP-transportationMaximumHumidityMaximum
	transportationHumidityMinimum + UoM	Numeric + Code List	The minimum humidity in percentages in which the trade items should be transported.	AVP-transportationMaximumHumidityMinimum
High Value	transportationHumidityMaximum + UoM	Numeric + Code List	The maximum humidity in percentages in which the	GUDID Code for Storage Type- Handling environment humidity

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
Unit of Measure			trade items should be transported.	
Low Value	transportationHumidityMinimum + UoM	Numeric + Code List	The minimum humidity in percentages in which the trade items should be transported.	GUDID Code for Storage Type- Handling environment humidity
Unit of Measure				
Storage and Handling Type	transportationMaximumTemperature + UoM	Numeric + Code List	The maximum temperature that a trade item can be held at during transport as defined by the manufacturer without affecting product safety or quality.	GUDID Code for Storage Type- Handling environment temperature
	transportationMinimumTemperature + UoM	Numeric + Code List	The minimum temperature that a trade item can be held below during transport as defined by the manufacturer without affecting product safety or quality.	GUDID Code for Storage Type- Handling environment temperature
High Value	transportationMaximumTemperature + UoM	Numeric + Code List	The maximum temperature that a trade item can be held at during transport as defined by the manufacturer without affecting product safety or quality.	GUDID Code for Storage Type- Handling environment temperature
Unit of Measure				
Low Value	transportationMinimumTemperature + UoM	Numeric + Code List	The minimum temperature that a trade item can be held below during transport as defined by the manufacturer without affecting product safety or quality.	GUDID Code for Storage Type- Handling environment temperature
Unit of Measure				
Special Storage Conditions	consumerUsageStorageInstructions	Text (1 to 1000 characters)	Expresses in text the consumer storage and usage instructions of a product which are normally held on the label or accompanying the product. This information may or may not be labelled on the pack. Instructions may refer to a suggested storage temperature, a specific storage requirement or a reference to environment or duration. Examples include: “Refrigerate After Opening”,	

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
			"Consume within 4 days" "Keep Out Of Direct Sunlight" ,"Store at an Ambient Temperature", "Store in a Clean, Cool, Dry Place", "Store Away From Sunlight, Strong Odours and Chemicals", "Keep in a Clean, Cool, Dry and Odourless Place Away From Direct Sunlight and Freezing Temperatures", "Keep in a Clean, Cool, Dry and Odourless Place Away From Direct Sunlight", "Before opening store at + 5°C+ 30°C", "After Opening Keep Refrigerated (+5°C) and Consume Within 48 hours", "Drink Chilled", "Store in a Cool Dry Place", "Refrigerate After Opening. Can Be Kept in the Fridge For 3 Months".	
Sterilization Method				
Device Packaged as Sterile	initialManufacturerSterilisation	Code List	Type(s) of sterilisation that may have been performed by the manufacturer if a trade item is sterile when it comes from the manufacturer. Sterilisation refers to any process that effectively kills or eliminates transmissible agents (such as fungi; bacteria; viruses; prions and spore forms etc.) from a surface; equipment; foods; medications; or biological culture medium. Some methods of sterilisation are through the application of heat; radiation; and ethylene.	LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of any value in initialManufacturerSterilisation)
Requires Sterilization Prior to Use	Data Pool to default on outbound message			LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of any value in initialSterilisationPriorToUse)
Sterilization Method	initialSterilisationPriorToUse	Code List	This is an indication of the type(s) of sterilisation that is required to be completed by a healthcare provider prior to initial use of the healthcare trade item. Sterilisation refers to	

FDA GUDID Data Element	GS1 GDSN Attribute Name	GDSN Data Type	GDSN Definition	GDSN Notes
			any process that effectively kills or eliminates transmissible agents (such as fungi; bacteria; viruses; prions and spore forms etc.) from a surface; equipment; foods; medications; or biological culture medium. Some methods of sterilisation are through the application of heat; radiation; and ethylene.	

5. FDA GUDID mapping to GS1 code values

The list below are FDA GUDID code values mapped to GS1 GDSN Code values. For some of these attributes, there may be additional code values available for use in GDSN not listed. This list focuses on just the values applicable to the GUDID mapping. Where the terming “PENDING” is utilized, it means actual code values have either not been identified by the FDA, or that a code is in process with the Global Standards Management Process (GSMP), but not yet assigned.

FDA GUDID Attribute	Code Value
Version or Model Number	

GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Additional Trade Item Identification Type	MODEL_NUMBER		(Current definition)- Additional Vendor identification number, which defines the configuration of the product over and above the Item number. (Definition for GDSN Major Release 3.x in 2016)- The additional Trade Item Identification value populated is an identification number which defines the configuration of the product in addition to the Item number. This is typically printed or otherwise attached to an item. In electronics, this number is typically found around or near a serial number.

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Catalog Number		Additional Trade Item Identification Type	SUPPLIER_ASSIGNED		(Current definition)- The additional Trade Item Identification value populated has been developed and assigned by the party which provides service(s) and/or manufactures or otherwise has possession the goods and consigns or makes them available in trade. (Definition for GDSN Major Release 3.x in 2016)- The additional Trade Item Identification value populated has been developed and assigned by the party which provides service(s) and/or manufactures or otherwise has possession of the goods and consigns or makes them available in trade. This number is a base model or style number assigned to the product and may be the same for several GTINs where they are variations of each other. For example a coffee mug with 3 GTINs one each for the brown mug, the white mug, and the black mug might all be the supplier assigned number of AB123. Use of this value is recommended in the absence of a Model Number or Manufacturer's Part Number.
UoM- Storage and Handling Type\Unit of Measure	Pending	UoM- UN Recommendation 20	64	Pound per square inch - Gauge	Psig (pound-force per square inch gauge) is a unit of pressure relative to the surrounding atmosphere. At sea level, Earth's atmosphere actually exerts a pressure of 14.7 psi. Humans do not feel this pressure because internal pressure of liquid in their bodies matches the external pressure. If a pressure gauge is calibrated to read zero in space, then at sea level on Earth it would read 14.7 psi. Thus a reading of 30 psig, on Earth, on a tire gauge represents an absolute pressure of 44.7 psi (lb/in^2).
UoM-	Pending	UoM- UN Recommendation 20	58	Net kilogram	A unit of mass defining the total number of kilograms after deductions.
UoM-	Pending	UoM- UN Recommendation 20	2N	Decibel	A measurement for sound in air and other gases, relative to 20 micropascals (μPa) = 2×10−5 Pa, the quietest sound a human can hear.

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
					This is roughly the sound of a mosquito flying 3 metres away. This is often abbreviated to just "dB"; however the correct abbreviation is dB(SPL), indicating decibel for Sound Pressure Level.
UoM-	Pending	UoM- UN Recommendation 20	2P	Kilobyte	A unit of information equal to 10^3 (1000) bytes.
UoM-	Pending	UoM- UN Recommendation 20	4G	Microlitre	A microlitre is one millionth of a litre
UoM-	Pending	UoM- UN Recommendation 20	4L	Megabyte	A unit of information equal to 10^6 (1000000) bytes.
UoM-	Pending	UoM- UN Recommendation 20	A86	Gigahertz	A unit of frenquecy equal to 109 Hertz
UoM-	Pending	UoM- UN Recommendation 20	AD	Byte	A unit of information equal to 8 bits.
UoM-	Pending	UoM- UN Recommendation 20	ANN	Year	Unit of time equal to 365,25 days.
UoM-	Pending	UoM- UN Recommendation 20	APZ	Troy ounce or apothecary ounce	The troy ounce is a unit of imperial measure. In the present day it is most commonly used to gauge the weight and therefore the price of precious metals. One troy ounce equals 480 grains or 31.1035 grams.
UoM-	Pending	UoM- UN Recommendation 20	BB	Base box	A unit of area of 112 sheets of tin mil products (tin plate, tin free steel or black plate) 14 by 20 inches, or 31,360 square inches.
UoM-	Pending	UoM- UN Recommendation 20	BFT	Board Foot	A specialized unit of measure for the volume of rough lumber (before drying and planing with no adjustments) or planed/surfaced lumber. It is the volume of a one-foot length of a board one foot wide and one inch thick. Some countries utilize the synonym super foot or superficial foot.
UoM-	Pending	UoM- UN Recommendation 20	BLL	Barrel US	There are varying standards for barrel for some specific commodities, including 31 gal for beer, 40 gal for whiskey or kerosene, and 42 gal for petroleum. The general standard for liquids is 31.5 gal or half a hogshead; the general standard for dry contents is 7,056 Cubic Inches.
UoM-	Pending	UoM- UN Recommendation 20	BP	Hundred board foot	A unit of volume equal to one hundred board foot.
UoM-	Pending	UoM- UN Recommendation 20	BTU	British thermal unit	The British thermal unit (BTU or Btu) is a traditional unit of energy. It is

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
					approximately the amount of energy needed to heat one pound of water one degree Fahrenheit. One Btu is equal to about 1.06 kilojoules. It is used in the power, steam generation, heating and air conditioning industries.
UoM-	Pending	UoM- UN Recommendation 20	BUA	Bushel (US)	A bushel is an imperial and U.S. customary unit of dry volume, equivalent in each of these systems to 4 pecks or 8 gallons. It is used for volumes of dry commodities (not liquids), most often in agriculture
UoM-	Pending	UoM- UN Recommendation 20	BUI	Bushel (UK)	A bushel is an imperial and U.S. customary unit of dry volume, equivalent in each of these systems to 4 pecks or 8 gallons. It is used for volumes of dry commodities (not liquids), most often in agriculture
UoM-	Pending	UoM- UN Recommendation 20	C26	Millisecond	A millisecond (from milli- and second; abbreviation: ms) is a thousandth (1/1000) of a second.
UoM-	Pending	UoM- UN Recommendation 20	CG	Card	A unit of count defining the number of units of card (card: thick stiff paper or cardboard).
UoM-	Pending	UoM- UN Recommendation 20	CGM	Centigram	A centigram is one hundredth (1/100) of a gram
UoM-	Pending	UoM- UN Recommendation 20	CLT	Centimetre	A centimetre is equal to one hundredth of a metre.
UoM-	Pending	UoM- UN Recommendation 20	CMK	Square centimetre	A square centimetre is an area of a square whose sides are exactly 1 centimetre in length.
UoM-	Pending	UoM- UN Recommendation 20	CMQ	Cubic centimetre	A cubic centimetre is the volume of a cube of side length one centimetre (0.01 m) equal to a millilitre.
UoM-	Pending	UoM- UN Recommendation 20	CWA	Hundred pound (cwt) / hundred weight (US)	A unit of weight in the U.S. Customary System equal to 100 pounds (45.36 kilograms); also called cental.
UoM-	Pending	UoM- UN Recommendation 20	CWI	Hundred weight (UK)	A unit of weight in the British Imperial System equal to 112 pounds (50.80 kilograms); also called quintal.
UoM-	Pending	UoM- UN Recommendation 20	D29	Terahertz	A unit of frenquecy equal to 1012 Hertz
UoM-	Pending	UoM- UN Recommendation 20	D30	Terajoule	A terajoule is 10^{12} joules
UoM-	Pending	UoM- UN Recommendation 20	D32	Terawatt hour	A terawatt hour is 109 * kilowat hour or 3.6 petajoules.
UoM-	Pending	UoM- UN Recommendation 20	D63	Book	A unit of count defining the number of books (book: set of items bound

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
					together or written document of a material whole).
UoM-	Pending	UoM- UN Recommendation 20	DAY	Days	A day is one three hundreds and sixty fifth (1/365) of a year
UoM-	Pending	UoM- UN Recommendation 20	DD	Degree (Unit of Angel)	A measurement of plane angle, representing 1⁄360 of a full rotation; one degree is equivalent to π/180 radians.
UoM-	Pending	UoM- UN Recommendation 20	DG	Decigram	A decigram is one tenth (1/10) of a gram.
UoM-	Pending	UoM- UN Recommendation 20	DLT	Decilitre	A decilitre is one tenth (1/10) of a litre.
UoM-	Pending	UoM- UN Recommendation 20	DMK	Square decimetre	A square deciimetre is an area of a square whose sides are exactly 1 deciimetre in length.
UoM-	Pending	UoM- UN Recommendation 20	DMQ	Cubic decimetre	A cubic decimetre is the volume of a cube of side length one decimetre (0.1 m)
UoM-	Pending	UoM- UN Recommendation 20	E34	Gigabyte	A unit of information equal to 109 bytes.
UoM-	Pending	UoM- UN Recommendation 20	E35	Terabyte	A unit of information equal to 10^{12} bytes.
UoM-	Pending	UoM- UN Recommendation 20	E4	Gross kilogram	A unit of mass defining the total number of kilograms before deductions.
UoM-	Pending	UoM- UN Recommendation 20	FTK	Square foot	A square foot is an area of a square whose sides are exactly 1 foot in length.
UoM-	Pending	UoM- UN Recommendation 20	FTQ	Cubic foot	A cubic foot is the volume of a cube of side length one foot (0.3048 m) .
UoM-	Pending	UoM- UN Recommendation 20	G23	Peck	A peck is an imperial and U.S. customary unit of dry volume, equivalent in each of these systems to 2 gallons, 8 dry quarts, or 16 dry pints.
UoM-	Pending	UoM- UN Recommendation 20	GLI	Gallon (UK)	The imperial (UK) gallon was legally defined as 4.54609 litres.
UoM-	Pending	UoM- UN Recommendation 20	GLL	Gallon (US)	The U.S. liquid gallon is legally defined as 231 cubic inches, and is equal to exactly 3.785411784 litres or about 0.133680555 cubic feet.
UoM-	Pending	UoM- UN Recommendation 20	GM	Gram per square metre	In the metric system, the density of all types of paper, paperboard, and fabric, is expressed in terms of grams per square meter (g/m^2). This quantity is commonly called grammage both in English and French (ISO 536), though many English-speaking countries still refer to the "weight". The term density

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
						here is used somewhat incorrectly, as density is mass by volume. More precisely, it is a measure of the area density, areal density, or surface density.
UoM-	Pending		UoM- UN Recommendation 20	GRM	Gram	A gram is defined as one one-thousandth of the kilogram (1×10-3 kg).
UoM-	Pending		UoM- UN Recommendation 20	GRN	Grain	A grain or troy grain is precisely 64.79891 milligrams. Exactly 7,000 grains per avoirdupois pound.
UoM-	Pending		UoM- UN Recommendation 20	GRO	Gross	A unit of count defining the number of units in multiples of 144 (12 x 12).
UoM-	Pending		UoM- UN Recommendation 20	GWH	Gigawatt hour	A gigaawatt hour is 109 kilowat hour or 3.6 terajoules.
UoM-	Pending		UoM- UN Recommendation 20	HC	Hundred count	A unit of count defining the number of units counted in multiples of 100.
UoM-	Pending		UoM- UN Recommendation 20	HD	Half dozen	A unit of count defining the number of units in multiplt of six (6).
UoM-	Pending		UoM- UN Recommendation 20	HGM	Hectogram	A hectogram is one hundred (100) grams
UoM-	Pending		UoM- UN Recommendation 20	HLT	Hectolitre	A hectolitre is one hundred (100) litres.
UoM-	Pending		UoM- UN Recommendation 20	HTZ	Hertz	A unit of frequency defined as the number of complete cycles per second; it is the basic unit of frequency in the International System of Units (SI).
UoM-	Pending		UoM- UN Recommendation 20	HUR	Hour	An hour is a unit of measurement of time of the duration of 60 minutes, or 3600 seconds. It is 1/24 of a median Earth day.
UoM-	Pending		UoM- UN Recommendation 20	INK	Square inch	A square inch is an area of a square whose sides are exactly 1 inch in length.
UoM-	Pending		UoM- UN Recommendation 20	INQ	Cubic inch	A cubic inch is the volume of a cube of side length one inch (0.254 m).
UoM-	Pending		UoM- UN Recommendation 20	JOU	Joule	A joule is the energy exerted by a force of one newton acting to move an object through a distance of one metre.
UoM-	Pending		UoM- UN Recommendation 20	K6	Kilolitre	A kilolitre is one thousand (1000) litres.
UoM-	Pending		UoM- UN Recommendation 20	KGM	Kilogram	A unit of mass equal to one thousand grams.
UoM-	Pending		UoM- UN Recommendation 20	KHZ	Kilohertz	A unit of frenquecy equal to 103 Hertz
UoM-	Pending		UoM- UN Recommendation 20	KJO	Kilojoule	A kilojoule is 1000 joules

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
UoM-	Pending		UoM- UN Recommendation 20	KWH	Kilowatt hour	A kilowatt hour is a unit of energy equal to 3.6 megajoules. It is also a common commercial unit of electric energy representing the amount of energy delivered at a rate of 1,000 watts over a period of one hour.
UoM-	Pending		UoM- UN Recommendation 20	KWT	Kilowatt	A kilowatt is one thousand (1000) watts
UoM-	Pending		UoM- UN Recommendation 20	LBR	Pound	The international avoirdupois pound of exactly 0.45359237 kilogram.
UoM-	Pending		UoM- UN Recommendation 20	LR	Layer	A unit of count defining the number of layers.
UoM-	Pending		UoM- UN Recommendation 20	LTN	Ton (UK) or long ton (US)	Ton (UK) = 1016 Kg or 2240 Lb.
UoM-	Pending		UoM- UN Recommendation 20	LTR	Litre	A litre is defined as a special name for a cubic decimetre (1 L = 1 dm3 = 103 cm3).
UoM-	Pending		UoM- UN Recommendation 20	MAW	Megawatt	A unit of power defining the rate of energy transferred or consumed when a current of 1000 amperes flows due to a potential of 1000 volts at unity power factor.
UoM-	Pending		UoM- UN Recommendation 20	MC	Microgram	A microgram is one millionth of a gram (0.000001)
UoM-	Pending		UoM- UN Recommendation 20	MGM	Milligram	A milligram is one thousandth of a gram (0.001)
UoM-	Pending		UoM- UN Recommendation 20	MHZ	Megahertz	A unit of frenquecy equal to 106 Hertz
UoM-	Pending		UoM- UN Recommendation 20	MIK	Square mile	A square mile is an area of a square whose sides are exactly 1 mile in length.
UoM-	Pending		UoM- UN Recommendation 20	MIN	Minute (unit of time)	A minute is a unit of time equal to 1/60th of an hour or 60 seconds
UoM-	Pending		UoM- UN Recommendation 20	MLT	Millilitre	A millilitre is one thousandth of a litre (0.001)
UoM-	Pending		UoM- UN Recommendation 20	MMK	Square millimetre	A square millimetre is an area of a square whose sides are exactly 1 millimetre in length.
UoM-	Pending		UoM- UN Recommendation 20	MMQ	Cubic millimetre	A cubic millimetre is the volume of a cube of side length one milliimetre (0.001 m)
UoM-	Pending		UoM- UN Recommendation 20	MON	Month	Unit of time equal to 1/12 of a year of 365,25 days
UoM-	Pending		UoM- UN Recommendation 20	MTK	Square metre	A square metre is an area of a square whose sides are exactly 1 metre in length.
UoM-	Pending		UoM- UN Recommendation 20	MTQ	Cubic metre	A cubic metre is the volume of a cube of side length one metre.

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
UoM-	Pending		UoM- UN Recommendation 20	MWH	Megawatt hour (1000 kW.h)	A unit of energy defining the total amount of bulk energy transferred or consumed.
UoM-	Pending		UoM- UN Recommendation 20	ONZ	Ounce	A unit of mass with several definitions, the most commonly used of which are equal to approximately 30 grams
UoM-	Pending		UoM- UN Recommendation 20	OZA	Fluid ounce (US)	A fluid ounce (US) is equal to one sixteenth (1/16) of a US pint or 29.5735295625 millilitres .
UoM-	Pending		UoM- UN Recommendation 20	OZI	Fluid ounce (UK)	A fluid ounce (UK) is equal to one thirtieth (1/30) of a UK pint or 28.4130625 millilitres.
UoM-	Pending		UoM- UN Recommendation 20	P1	Percent	A unit of proportion equal to 0.01.
UoM-	Pending		UoM- UN Recommendation 20	PD	Pad	A unit of count defining the number of pads (pad: block of paper sheets fastened together at one end).
UoM-	Pending		UoM- UN Recommendation 20	PR	Pair	A unit of count defining the number of pairs (pair: item described by two's).
UoM-	Pending		UoM- UN Recommendation 20	PTD	Dry Pint (US)	The United States dry pint is equal one eighth of a US dry gallon or one half US dry quarts. It is used in the United States but is not as common as the liquid pint.
UoM-	Pending		UoM- UN Recommendation 20	PTI	Pint (UK)	A pint (UK) is equal to 1/8 Gallon (UK); used primarly as a measure for beer and cider when sold by the glass.
UoM-	Pending		UoM- UN Recommendation 20	PTL	Liquid pint (US)	The US liquid pint is equal one eighth of a United States liquid gallon.
UoM-	Pending		UoM- UN Recommendation 20	QB	Page - hardcopy	A unit of count defining the number of hardcopy pages (hardcopy page: a page rendered as printed or written output on paper, film, or other permanent medium).
UoM-	Pending		UoM- UN Recommendation 20	QTD	Quart (US dry)	A US dry quart is equal to 1/32 of a US bushel, exactly 1.101220942715 litres.
UoM-	Pending		UoM- UN Recommendation 20	QTL	Liquid quart (US)	A US liquid quart exactly equals 57.75 cubic inches, which is exactly equal to 0.946352946 litres.
UoM-	Pending		UoM- UN Recommendation 20	SEC	Second (unit of time)	A second is a unit of time equal to 1/60th of an minute.
UoM-	Pending		UoM- UN Recommendation 20	STN	Ton (US) or short ton (UK)	Ton (US) = 2000 Lb or 907 Kg
UoM-	Pending		UoM- UN Recommendation 20	SX	Shipment	A unit of count defining the number of shipments (shipment: an amount of goods shipped or transported).

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
UoM-	Pending		UoM- UN Recommendation 20	TNE	Tonne	Metric ton = 1000 Kg
UoM-	Pending		UoM- UN Recommendation 20	U2	Tablet	A unit of count defining the number of tablets (tablet: a small flat or compressed solid object).
UoM-	Pending		UoM- UN Recommendation 20	WEE	Week	A week is a time unit equal to seven days.
UoM-	Pending		UoM- UN Recommendation 20	WHR	Watt hour	The watt-hour is a unit of energy equivalent to one watt of power expended for one hour of time; it is equal to 3.6 kilojoules. The watt-hour is rarely used to express energy in any form other than electrical.
UoM-	Pending		UoM- UN Recommendation 20	WTT	Watt	A watt is a derived unit of power; one watt is equivalent to 1 joule (J) of energy per second.
UoM-	Pending		UoM- UN Recommendation 20	YDK	Square Yard	A square yard is the area of a square with sides of one yard (three feet, thirty-six inches, 0.9144 metres) in length
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	5B	Batch	A unit of count defining the number of batches (batch: quantity of material produced in one operation or number of animals or persons coming at once).
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	AS	Assortment	A unit of count defining the number of assortments (assortment: set of items grouped in a mixed collection).
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	CMT	Centimetre	A centimetre is equal to one hundredth of a metre.
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	DMT	Decimetre	A decimetre is equal to one tenth of a metre.
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	DZN	Dozen	A unit of count defining the number of units in multiples of 12.
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	E27	Dose	A unit of count defining the number of doses (dose: a definite quantity of a medicine or drug).
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	E55	Use	A unit of count defining the number of times an object is used.
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	EA	Each	A unit of count defining the number of items regarded as separate units.
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	FOT	Foot	The international foot is defined to be equal to 0.3048 meters.
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	H87	Piece	A unit of count defining the number of pieces (piece: a single item, article or exemplar).
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	INH	Inches	An international inch is defined to be equal to 25.4 millimeters.
UoM- Size Unit of Measure	Pending		UoM- UN	KMT	Kilometre	A kilometre is one thousand (1000)

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
			Recommendation 20			metres
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	KT	Kit	A unit of count defining the number of kits (kit: tub, barrel or pail).
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	LF	Linear foot	A unit of count defining the number of feet (12-inch) in length of a uniform width object.
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	LK	Link	A unit of distance equal to 0.01 chain.
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	LM	Linear metre	A unit of count defining the number of metres in length of a uniform width object.
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	MMT	Millimetre	A millimetre is one thousandth of a metre (0.001)
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	MTR	Metre	The metre is the basic unit of length in the International System of Units (SI).
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	NIU	Number of International Units	A unit of count defining the number of international units. The International Unit is a unit of measurement for the amount of a substance, based on measured biological activity or effect. The unit is used for vitamins, hormones, some medications, vaccines, blood products, and similar biologically active substances
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	SET	Set	A unit of count defining the number of sets (set: a number of objects grouped together).
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	SMI	Mile (statute mile)	A statute mile of 5,280 feet (exactly 1,609.344 meters).
UoM- Size Unit of Measure	Pending		UoM- UN Recommendation 20	YRD	Yard	A yard is It is equal to 3 feet or 36 inches or 0.9144 meter.
UoM- Storage and Handling Type\Unit of Measure	Pending		UoM- UN Recommendation 20	28	Kilogram per square metre	A unit of pressure equal to 9.80665*10-05 Bar
UoM- Storage and Handling Type\Unit of Measure	Pending		UoM- UN Recommendation 20	BAR	Bar (unit of pressure)	The bar is widely used in descriptions of pressure; 1 bar = 100 kilopascals 0.987 atmospheres.
UoM- Storage and Handling Type\Unit of Measure	Pending		UoM- UN Recommendation 20	CEL	Degree Celsius	Celsius (also historically known as centigrade) is a temperature scale, the freezing point of water is 0 degrees Celsius (°C) and the boiling point 100 °C (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 100 degrees apart.
UoM- Storage and Handling Type\Unit of Measure	Pending		UoM- UN Recommendation 20	D5	Kilogram per square centimetre	A kilogram-force per square centimeter (kgf/cm2), often just kilogram per square centimeter (kg/cm2), or kilopond per square centimeter is a unit of pressure using

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
						metric units. Its use is now deprecated; it is not a part of the International System of Units (SI), the modern metric system. The unit is similar to the English unit psi (lbf/in2).
UoM- Storage and Handling Type\Unit of Measure	Pending		UoM- UN Recommendation 20	FAH	Degree Fahrenheit	The Fahrenheit temperature scale, the freezing point of water is 32 degrees Fahrenheit (°F) and the boiling point 212 °F (at standard atmospheric pressure), placing the boiling and freezing points of water exactly 180 degrees apart.
UoM- Storage and Handling Type\Unit of Measure	Pending		UoM- UN Recommendation 20	FP	Pound per square foot	A non SI unit of Pressure approximately equal to 47.88025 PASCAL's.
Contact	Used to provide Contact Information for GUDID		Contact Type	CONSUMER_SUPPORT		The party which provides product support to the end user of a trade item or a service.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_EGG		Marks if the product is free from egg.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_FISH		The item is physically marked as being free from fish, as approved by the appropriate authority of the target market.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_GLUTEN		Marks if the product is free from gluten. This level of containment is frequently determined through regulation for example per EU Regulation (EC) No 41/2009 [of 20 January 2009], this is defined as =< 20 mg/kg).
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_LACTOSE		Indicates if the amount of lactose is reduced.
Device labeled as "Not made with natural rubber latex"	TRUE		packageMarksFreeFrom	FREE_FROM_LATEX		The item is physically marked being free from Latex (rubber) as approved by the appropriate authority of the target market.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_LEGUME_PROTEIN		The item is physically marked as being free from legume protein, as approved by the appropriate authority of the target market.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_MILK		The item is physically marked as being free from milk and any of its derivates, as approved by the appropriate authority of the target market.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_MILK_PROTEIN		Free from milk protein.
Device labeled as "Not made with	FALSE		packageMarksFreeFrom	FREE_FROM_NATURA		The item is physically marked as

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
natural rubber latex"				L_GLUTEN		being naturally free from gluten and not extracted as part of the manufacturing process, as approved by the appropriate authority of the target market.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_PEANUTS		Marks if the product is free from peanuts.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_PROTEIN		The item is physically marked as being free from protein, as approved by the appropriate authority of the target market.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_PVC		The item is physically marked as being free from PVC (Polyvinyl chloride), as approved by the appropriate authority of the target market.
Device labeled as "Not made with natural rubber latex"	FALSE		spackageMarksFreeFrom	FREE_FROM_SOYA		Free from soya.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	FREE_FROM_SUGAR		Marks if the product is free from sugar.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	REDUCED_LACTOSE		Indicates if the amount of lactose is reduced.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	REDUCED_PROTEIN		The item is physically marked as containing a low level of protein as approved by the appropriate authority of the target market.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	VERY_LOW_GLUTEN		The item is physically marked as as a very low amount of gluten. Very low is frequently determined through regulation for example, per EU Regulation (EC) No 41/2009 [of 20 January 2009], this is defined as containing between 20 and 100 mg/kg).
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	WITHOUT_ADDED_SUGAR		The item is physically marked that no sugar has been added when manufacturing the product but it still can contain sugars that are naturally part of the ingredients, as approved by the appropriate authority of the target market.
Device labeled as "Not made with natural rubber latex"	FALSE		packageMarksFreeFrom	WITHOUT_ADDED_SWEETENER		The item is physically marked that no sweetener has been added when manufacturing the product as approved by the appropriate authority of the target market.
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR	FALSE		Does Trade Item Contain Latex	FALSE		The Brand Owner labeling does not state the Trade Item contains latex or may state that the Trade Item is free

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
801.437)						from latex.
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	TRUE		Does Trade Item Contain Latex	TRUE		Brand Owner labeling states the Trade Item contains latex.
Expiration Date	TRUE		Packaging Marked Expiration Date Type	BEST_BEFORE_DATE		Not Applicable
Expiration Date	TRUE		Packaging Marked Expiration Date Type	EXPIRY_DATE		Not Applicable
Expiration Date	Other values or no value populated equates to a value of FALSE		Packaging Marked Expiration Date Type			
FDA Premarket Submission Number FDA Product Code	GMDN		Additional Classificaiton Category Type	35	GMDN	Global Medical Devices Nomenclature (GMDN)
FDA Premarket Submission Number FDA Product Code	FDA Product Code		Additional Classificaiton Category Type	43	FDA Product Code	US FDA Product Code Classification Database: The Product Classification Database contains medical device names and associated information developed by the Center for Devices and Radiological Health (CDRH) in support of its mission. This database contains
For GDS Use Only			Additional Classificaiton Category Type	5	UNSPSC	UNSPSC: United Nations Standard Products and Services Code
For GDS Use Only			Additional Classificaiton Category Type	6	UNSPSC- ECCMA	UNSPSC - Electronic Commerce Code Management Association
For Single Use	FALSE		Healthcare Trade Item Reusability	LIMITED_REUSABLE		Manufacturer has indicated that product may be reused but has provided special instructions, limitations or guidelines around the reuse of this trade item.
For Single Use	FALSE		Healthcare Trade Item Reusability	REUSABLE		Product can be reused
For Single Use	TRUE		Healthcare Trade Item Reusability	REUSABLE_SAME_PATIENT		Product can only be reused for the same patient.
For Single Use	TRUE		Healthcare Trade Item Reusability	SINGLE_USE		Item is not intended to be reused.
Labeler DUNS			Additional Party Identification Type	DUNS		N/A
Labeler DUNS			Additional Party Identification Type	DUNS_PLUS_FOUR		N/A
MRI Safety Status	MR Conditional		mRICompatibility	MRI_Conditional		Indicates that a healthcare trade item is safe to use under specified conditions in a Magnetic Resonance Imaging (MRI) System
MRI Safety Status	MR Safe		mRICompatibility	MRI_Safe		Indicates tht the healthcare trade item is safe to use within a Magnetic

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
						Resonance Imaging (MRI) system.
MRI Safety Status	MR Unsafe		mRICompatibility	MRI_Unsafe		Indicates that a healthcare trade item is not safe to use in an MRI system.
MRI Safety Status	MR Unsafe		mRICompatibility	UNSPECIFIED		The manufacturer of the Trade Item has not communicated information on the compatibility of this trade item with a Magnetic Resonance Imaging (MRI) System.
Over the Counter (OTC)	Over the Counter (OTC)		Consumer Sales Conditions	OTC		Over the Counter- products that may be sold without a prescription. These products are generally available without restrictions.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	AAA	Pallet, Returnable	Pallet, Returnable
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	AAB	Splash Blend	Splash Blend- Splash blending is the mixing of two gasoline products, of different octane levels, in a tank on the delivery vehicle to produce a third blended grade of motor fuel for resale
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	AE	Aerosol	Aerosol: A gas-tight, pressure-resistant container with a valve and propellant. When the valve is opened, propellant forces the product from the container in a fine or coarse spray pattern or stream. (e.g., a spray can dispensing paint, furniture polish
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	AMM	Ammo Pack	Ammo Pack

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	AMP	Ampoule	Ampoule: A relatively small container made from glass or plastic tubing, the end of which is drawn into a stem and closed by fusion after filling. The bottom may be flat, convex, or drawn out. An ampule is opened by breaking the stem.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	AT	Atomizer	Atomizer: A device for reducing a liquid to a fine spray. (e.g., medicine, perfume, etc). An atomizer does not rely on a pressurised container for the propellant. Usually air is provided by squeezing a rubber bulb attached to the atomizer.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	ATH	Attachment	Attachment: In containers and shipping devices, a component that can be added to provide additional functionality or security as required by the contents or method of transportation/handling
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BAG	Bag	Bag: A preformed, flexible container, generally enclosed on all but one side, which forms an opening that may or may not be sealed after filling.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BAL	Bale	Bale
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	BBL	Barrel	Barrel: A cylindrical packaging whose bottom end is permanently fixed to the body and top end (head) is either removable or non-removable.

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
	the description field at right should be passed to the FDA GUDID.				
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BDG	Banding	Banding: Something that binds, ties, or encircles the package/container to secure and maintain unit integrity
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BDL	Bundle	Bundle
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BEM	Beam	Beam
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BIC	Bing Chest	Bing Chest
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BIN	Bin	Bin

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BLK	Bulk	Bulk
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BLT	Belting	Belting:As pertains to containers and shipping devices, a method of securing the contents to the conveyance device (or securing components of the shipping device to each other) using one or more bands of flexible material having high-tensile strength and
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BME	Blister Pack	Blister Pack: A type of packaging in which the item is secured between a preformed (usually transparent plastic) dome or “bubble” and a paperboard surface or “carrier.” Attachment may be by stapling, heat-sealing, gluing, or other means. In other instan
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BOB	Bobbin	Bobbin
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BOT	Bottle	Bottle: A container having a round neck of relatively smaller diameter than the body and an opening capable of holding a closure for retention of the contents. Specifically, a narrow-necked container as compared with a jar or wide-mouth container. The c
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	BOX	Box	Box: A non-specific term used to refer to a rigid, three-dimensional container with closed faces that completely enclose its contents and may be made out of any material. Even

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
	the description field at right should be passed to the FDA GUDID.				though some boxes might be reused or become resealed they could also be disposa
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BRC	Bracing	Bracing:Material or devices used to hold articles or sections of loads in position to prevent shifting during transportation
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BRG	Barge	Barge
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BSK	Basket or hamper	Basket or hamper: A semi rigid container usually open at the top traditionally used for gathering, shipping and marketing agricultural products.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BXI	Box, with inner container	Box, with inner container
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	BXT	Bucket	Bucket: A container, usually cylindrical, can be equipped with a lid and a handle. (e.g., a pail made of metal, plastic, or other appropriate material).

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CAB	Cabinet	Cabinet
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CAG	Cage	Cage: A container enclosed on at least one side by a grating of wires or bars that lets in air and light.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CAN	Can	Can: A metallic and generally cylindrical container of unspecified size which can be used for items of consumer and institutional sizes.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CAR	Carrier	Carrier
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CAS	Case	Case: A non-specific term for a container designed to hold, house, and sheath or encase its content while protecting it during distribution, storage and/or exhibition. Cases are mostly intended to store and preserve its contents during the product's entir
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	CBC	Containers of Bulk Cargo	Containers of Bulk Cargo

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
	the description field at right should be passed to the FDA GUDID.					
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	CBY	Carboy	Carboy
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	CCS	Can Case	Can Case
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	CG	Card	Card: A flat package to which the product is hung or attached for display.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	CHE	Cheeses	Cheeses
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	CHS	Chest	Chest

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CLD	Car Load, Rail	Car Load, Rail
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CMS	Clamshell	Clamshell
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CNA	Household Goods Container, Wood	Household Goods Container, Wood
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CNB	Container, MAC-ISO, LT. WGT. 8x8x20 Foot Air	Container, MAC-ISO, LT. WGT. 8x8x20 Foot Air
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CNC	Container, Navy Cargo Transporter	Container, Navy Cargo Transporter
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	CND	Container, Commercial Highway Lift	Container, Commercial Highway Lift

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
	the description field at right should be passed to the FDA GUDID.				
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CNE	Container, Engine	Container, Engine
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CNF	Container, Multi-walled, Secured to Warehouse Pallet	Container, Multi-walled, Secured to Warehouse Pallet
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CNT	Container	Container
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	COL	Coil	Coil
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CON	Cones	Cones

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	COR	Core	Core
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CRD	Cradle	Cradle
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CRF	Corner Reinforcement	Corner Reinforcement: Usually in boxes or crates, additional material or components attached to adjacent panels to add support or prevent crushing or separation
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CRT	Crate	Crate: A non-specific term usually referring to a rigid three-dimensional container with semi-closed faces that enclose its contents for shipment or storage. Crates could have an open or closed top and may have internal divers. Even though some crates mig
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CSK	Cask	Cask
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	CTN	Carton	Carton: A non-specific term for a re-closable container used mostly for perishable foods (e.g. eggs, fruit).

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
	the description field at right should be passed to the FDA GUDID.				
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CU	Cup	Cup: A small bowl shaped container for beverages, often with a handle.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CX2	CONEX	CONEX: A reusable container for shipment of cargo
Packaging Type	GDSN utilizes the code value; however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	CYL	Cylinder	Cylinder: A rigid cylindrical container with straight sides and circular ends of equal size.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	DBK	Dry Bulk	Dry Bulk
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	DRK	Double-length Rack	Double-length Rack

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	DRM	Drum	Drum
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	DSK	Double-length Skid	Double-length Skid
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	DTB	Double-length Tote Bin	Double-length Tote Bin
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	DUF	Duffelbag	Duffelbag
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	EGG	Egg Crating	Egg Crating: In containers and shipping devices, usually describes a type of interior dunnage which allows the contents to be individually segregated, horizontally and vertically, to provide protection during transportation and storage
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	ENV	Envelope	Envelope: A predominantly flat container of flexible material having only two faces, and joined at three edges to form an enclosure. The non-joined edge provides a filling

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
	the description field at right should be passed to the FDA GUDID.				opening, which may later be closed by a gummed or adhesive flap, heat seal, tie st
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	EPR	Edge Protection	Edge Protection: A right-angle piece placed over the outermost perimeter edges of a container to distribute pressure and prevent collapse or cutting from banding, strapping, or handling
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	FIR	Firkin	Firkin
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	FLO	Flo-bin	Flo-bin
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	FRM	Frame	Frame
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	FSK	Flask	Flask

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	FWR	Forward Reel	Forward Reel
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	GBG	Bag-In-Box or BIB	Bag-In-Box or BIB is a type of container for the storage and transportation of liquids. It consists of a strong bladder, usually made of aluminium PET film or other plastics seated inside a corrugated fibreboard box. The box and internal bag can be fused
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	GBR	Brick	Brick: A rectangular-shaped, stackable package designed primarily for liquids such as juice or milk.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	GGT	Gable Top	Gable Top: A rectangular-shaped, non-stackable package designed primarily for liquids such as juice or milk.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	GNT	Net	Net: A container of meshwork material made from threads or strips twisted or woven to form a regular pattern with spaces between the threads that is used for holding, carrying, trapping, or confining something.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	GPB	Pallet Box	Pallet Box: A three-dimensional container which either has a pallet platform permanently attached at its base or alternatively requires a platform for its handling and storage

FDA GUDID Attribute	Code Value		GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
	the description field at right should be passed to the FDA GUDID.					as due to its constitution it cannot be handled without it. The characteristics
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	GPP	Peel Pack	Peel Pack: A package used for sterile products which may be torn open without touching the product inside.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	GPU	Packed, Unspecified	Packed, Unspecified: Packaging of the product (or products) is currently not on the list. Use this code when no suitable options are available and only while a Change Request is approved for the proper packaging type.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	HPR	Hamper	Hamper
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	HPT	Hopper Truck	Hopper Truck
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.		Packaging Type Code	HRB	On Hanger or Rack in Boxes	On Hanger or Rack in Boxes

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	HRK	Half-Standard Rack	Half-Standard Rack
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	HTB	Half-Standard Tote Bin	Half-Standard Tote Bin
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	INT	Intermediate Container	Intermediate Container
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	JAR	Jar	Jar: A rigid container made of glass, stone, earthenware, plastic or other appropriate material with a large opening, which is used to store products, (e.g., jams, cosmetics).
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	JG	Jug	Jug: A container, normally cylindrical, with a handle and/or a lid or spout for holding and pouring liquids.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	KEG	Keg	Keg

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
	the description field at right should be passed to the FDA GUDID.				
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	KIT	Kit	Kit
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	KRK	Knockdown Rack	Knockdown Rack
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	KTB	Knockdown Tote Bin	Knockdown Tote Bin
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	LAB	Label Tag	Label Tag
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	LID	Lip/Top	Lip/Top: In packaging, the top or bottom of a container, usually the part that closes the opening; may also be known as cap, over, or top

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	LIF	Lifts	Lifts
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	LNR	Liners	Liners: Any material that separates a product within a container from the basic walls of the container
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	LOG	Log	Log
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	LSE	Loose	Loose
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	LUG	Lug	Lug
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	LVN	Lift Van	Lift Van

FDA GUDID Attribute	Code Value
	the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
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Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.

GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type Code	MIX	Mixed Container Types	Mixed Container Types: More than one type of container is included in a shipment (shipment could consist of 3 pieces that include 1 box, 1 crate, and 1 basket)\
Packaging Type Code	ML2	MILVAN	MILVAN: A military owned demountable container that conforms to US and international standards and operates in a centrally controlled fleet for movement of military cargo
Packaging Type Code	MPE	Multipack	Multipack
Packaging Type Code	MRP	Multi-Roll Pack	Multi-Roll Pack
Packaging Type Code	MS2	MSCVAN	MSCVAN:A commercial (leased) or Government-owned shipping container controlled by the Military Sealift Command.

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	MXD	Mixed	Mixed
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	NOL	Noil	Noil
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	PA	Packet	Packet
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	PAF	Pallet, 4- Way	Pallet – 4 Way:A pallet that permits entry of handling equipment on each of its four sides
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	PAL	Pail	Pail
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	PAT	Pallet, 2-way	Pallet - 2 Way:A pallet that permits entry of handling equipment on opposing two of its four sides

FDA GUDID Attribute	Code Value
	the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.

GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type Code	PCK	Packed	Packed - not otherwise specified
Packaging Type Code	PCS	Pieces	Pieces
Packaging Type Code	PIR	Pirns	Pirns
Packaging Type Code	PKG	Package	Package
Packaging Type Code	PLC	Primary Lift Container	Primary Lift Container:The largest (outermost) unitized package or articles secured together that can be handled (usually mechanically) in common shop floor/warehouse applications as a single entity; "primary" indicates preferred or mandatory

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	PLF	Platform	Platform
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	PLN	Pipeline	Pipeline
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	PLT	Pallet	Pallet: A platform used to hold or transport unit loads.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	PO	Pouch	Pouch: A preformed, flexible container, generally enclosed with a gusset seal at the bottom of the pack can be shaped/arranged to allow the pack to stand on shelf.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	POV	Private Vehicle	Private Vehicle
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	PRK	Pipe Rack	Pipe Rack

FDA GUDID Attribute	Code Value
	the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
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Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.

GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type Code	PRT	Partitioning	Partitioning: The proceeds of applying separators or dividers
Packaging Type Code	PUN	Punnet	Punnet
Packaging Type Code	PWT	Plastic-Wrapped Tray	Plastic-Wrapped Tray
Packaging Type Code	RAL	Rail (Semiconductor)	Rail (Semiconductor)
Packaging Type Code	RCK	Rack	A non-specific term identifying a framework or stand for carrying, holding, or storing items. Commonly on wheels and primarily used in the logistical functions to deliver items such as hanging garments, or items on shelves such as dairy products and baker

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	REL	Reel	Reel: A spool on which thread, wire, film, etc, is wound. Any device on which a material may be wound. Usually has flanged ends and is used for shipping or processing purposes.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	RFT	Reinforcement	Reinforcement:In containers and shipping devices, a component (usually temporary) added to a container for a particular application to lend additional support under severe applications
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	ROL	Roll	Roll
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	RVR	Reverse Reel	Reverse Reel
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SAK	Sack	Sack
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	SCS	Suitcase	Suitcase

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
	the description field at right should be passed to the FDA GUDID.				
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SHK	Shook	Shook
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SHT	Sheet	Sheet:A thin layer of material usually used as a pad for extra protection by isolating/separating tiers or layers of parts within the package
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SKD	Skid	Skid
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SKE	Skid, elevating or lift truck	Skid, elevating or lift truck
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SLP	Slip Sheet	Slip Sheet: Shipping containers utilizing slip sheets, which are cardboard platforms used to hold product for storage or transportation

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SLV	Sleeve	Sleeve: A non-rigid container usually made of paper, cardboard or plastic, that is open-ended and is slid over the contents for protection or presentation.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SPI	Spin Cylinders	Spin Cylinders
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SPL	Spool	Spool
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SPR	Separator/Divider	Separator/Divider:In packaging, any material inserted between tiers or layers of articles to prevent contact and provide protection
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SRW	Shrink Wrap	Shrink Wrap: In packaging, a plastic film around an item or group of items which is heated causing the film to shrink, securing the unit integrity. The use of shrunken film to tightly wrap a package or a unit load in order to bind, protect and immobilize
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	STW	Stretch Wrap	Stretch Wrap: In packaging, a high-tensile plastic film, stretched and wrapped repeatedly around an item or group of items to secure and maintain unit integrity. The use of stretch film

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
	the description field at right should be passed to the FDA GUDID.				to tightly wrap a package or a unit load in order to bind, protect a
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	SV2	SEAVAN	SEAVAN: A commercial or government-owned (or leased) shipping container which is moved via ocean transportation without wheels attached and is lifted on and off a ship
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	TBE	Tube	Tube: A cylindrical container sealed on one end that could be closed with a cap or dispenser on the other end.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	TBN	Tote Bin	Tote Bin
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	TKR	Tank Car	Tank Car
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	TKT	Tank Truck	Tank Truck

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	TLD	Intermodal Trailer/Container Load (Rail)	Intermodal Trailer/Container Load (Rail)
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	TNK	Tank	Tank
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	TRC	Tierce	Tierce
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	TRK	Trunk and Chest	Trunk and Chest
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	TRU	Truck	Truck
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	TRY	Tray	Tray: A shallow container, which may or may not have a cover, used for displaying or carrying items.

FDA GUDID Attribute	Code Value
	the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.

GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type Code	TSS	Trunk, Salesmen Sample	Trunk, Salesmen Sample
Packaging Type Code	TUB	Tub	Tub: Generally, a round flat-bottomed container closed with a large lid, typically used to contain ice cream, margarine, sour cream, confections, and other products.
Packaging Type Code	UNP	Unpacked	Unpacked: The item is provided without packaging.
Packaging Type Code	UNT	Unit	Unit
Packaging Type Code	UVQ	Wrapped in Plastic	Wrapped in Plastic

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	VEH	Vehicles	Vehicles
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	VIL	Vial	Vial
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	VOC	Vehicle in Operating Condition	Vehicle in Operating Condition
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	VP	Vacuum Packed	Vacuum Packed: Packaging in containers, either rigid or flexible, from which substantially all gases have been removed prior to final sealing of the container.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.	Packaging Type Code	VPK	Van Pack	Van Pack
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in	Packaging Type Code	WHE	On Own Wheel	On Own Wheel

FDA GUDID Attribute	Code Value
	the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Packaging Type	GDSN utilizes the code value, however GUDID currently needs a term for the code. The term in the description field at right should be passed to the FDA GUDID.
Prescription Use (Rx)	Prescription Use (Rx)
Secondary DI Issuing Agency	ICCBA
Secondary DI Issuing Agency	GS1
Secondary DI Issuing Agency	HIBCC
Secondary DI Issuing Agency/HIBCC	
Secondary DI Issuing Agency/ICCBBA	

GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Packaging Type Code	WLC	Wheeled Carrier	Wheeled Carrier
Packaging Type Code	WRP	Wrapped	Wrapped: The process of enclosing all or part of an item with layers of flexible wrapping material (e.g., for an individually packed ice cream). Does not include items which are shrink-wrapped or vacuum-packed.
Consumer Sales Conditions	PRESCRIPTION_REQUIRED		Trade item may only be sold or dispensed under the direction of a prescription.
Additional Trade Item Identification Type	GDSN Change Request (CR) in process to add this code value		
Additional Trade Item Identification Type			Not needed as there can only be one GTIN for an item and therefore cannot be a secondary GTIN.
Additional Trade Item Identification Type			Health Industry Business Communication Barcode: An alphanumeric identification number used as a common identifier within the healthcare industry across different locations. In the Netherlands, this code is managed by the European Health Industry Business
Additional Trade Item Identification Type	HIBC		Health Industry Business Communication Barcode: An alphanumeric identification number used as a common identifier within the healthcare industry across different locations. In the Netherlands, this code is managed by the European Health Industry Business
Additional Trade Item Identification Type	ICCBBA	GDSN Change Request (CR) is in process to add this	

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
				code value.	
Serial Number	TRUE	serialNumberLocationCode	MARKED_ON_PACKAGING		Serial number is on the trade item's packaging.
Serial Number	TRUE	serialNumberLocationCode	MARKED_ON_PACKAGING_INSERT		Serial number is on the trade item's packaging insert.
Serial Number	TRUE	serialNumberLocationCode	MARKED_ON_TRADE_ITEM		Serial number is on the trade item.
Serial Number	FALSE	serialNumberLocationCode	NOT_MARKED		The trade item or its packaging is not marked
Serial Number	FALSE	serialNumberLocationCode	UNKNOWN		Unknown location of marking.
SizeType	Circumference	Clinical SizeType	Circumference		
SizeType	Depth	Clinical SizeType	Depth		
SizeType	Device Size Text, specify	Clinical SizeType	Device Size Text, specify		
SizeType	French Catheter Gauge	Clinical SizeType	French Catheter Gauge		
SizeType	Greatest Diameter	Clinical SizeType	Greatest Diameter		
SizeType	Height	Clinical SizeType	Height		
SizeType	Length	Clinical SizeType	Length		
SizeType	Lumen Diameter	Clinical SizeType	Lumen Diameter		
SizeType	Needle Gauge	Clinical SizeType	Needle Gauge		
SizeType	Second Greatest Diameter	Clinical SizeType	Second Greatest Diameter		
SizeType	Third Greatest Diameter	Clinical SizeType	Third Greatest Diameter		
SizeType	Total Volume	Clinical SizeType	Total Volume		
SizeType	Width	Clinical SizeType	Width		
Sterilization Method	Moist Heat or Steam	Initial Manufacture Sterilization Initial Sterilization Prior to Use	AUTOCLAVE		Autoclave (Steam) is a method of sterilisation that utilizes pressure and heat to achieve a sterile environment.
Sterilization Method	Radiation	Initial Manufacture Sterilization Initial Sterilization Prior to Use	BETA_RADIATION		Beta particles are able to penetrate living matter to a certain extent (radiation intensity from a small source of radioactive material decreases as one over the distance squared) and can change the structure of struck molecules.
Sterilization Method	Ethylene Oxide	Initial Manufacture Sterilization Initial Sterilization Prior to Use	EtO_ETHYLENE_OXIDE		A gas that is commonly used to sterilize objects sensitive to temperatures greater than 60 °C such as plastics, optics and electrics. Ethylene oxide treatment is generally

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
					carried out between 30 °C and 60 °C with relative humidity above 30% and a gas conc
Sterilization Method	Radiation	Initial Manufacture Sterilization Initial Sterilization Prior to Use	GAMMA_RADIATION		Gamma rays are very penetrating and are commonly used for sterilization of disposable medical equipment, such as syringes, needles, cannulas and IV sets. Gamma radiation requires bulky shielding for the safety of the operators; they also require storage o
Sterilization Method	Dry Heat	Initial Manufacture Sterilization Initial Sterilization Prior to Use	GDSN Change Request (CR) in process to add this code value		
Sterilization Method	High Intensity Light or Pulse Light	Initial Manufacture Sterilization Initial Sterilization Prior to Use	GDSN Change Request (CR) in process to add this code value		
Sterilization Method	Microwave Radiation	Initial Manufacture Sterilization Initial Sterilization Prior to Use	GDSN Change Request (CR) in process to add this code value		
Sterilization Method	Sound Waves	Initial Manufacture Sterilization Initial Sterilization Prior to Use	GDSN Change Request (CR) in process to add this code value		
Sterilization Method	Hydrogen Peroxide	Initial Manufacture Sterilization Initial Sterilization Prior to Use	HYDROGEN_PEROXIDE		Another chemical sterilizing agent. It is relatively non-toxic once diluted to low concentrations (although a dangerous oxidizer at high concentrations), and leaves no residue.
Sterilization Method	Ozone	Initial Manufacture Sterilization Initial Sterilization Prior to Use	OZONE		Is a method often times used in industrial settings to sterilize water and air, as well as a disinfectant for surfaces. It has the benefit of being able to oxidize most organic matter. It is a toxic and unstable gas that must be produced on-site, so it is
Sterilization Method	Peracetic Acid	Initial Manufacture Sterilization Initial Sterilization Prior to Use	PERACETIC_ACID		A chemical in the organic peroxide family. It is a bright, colorless liquid with a characteristic acrid acetic acid type odor. It has a strong oxidizing potential, is highly corrosive, and can explode at temperatures exceeding 110 °C.
Sterilization Method	Ultraviolet Light	Initial Manufacture Sterilization Initial Sterilization Prior to Use	UV_light		Useful for sterilization of surfaces and some transparent objects. Many objects that are transparent to visible light absorb UV. UV irradiation is routinely

FDA GUDID Attribute	Code Value
Sterilization Method	Chlorine Dioxide
Storage and Handling Type	Storage Environment Atmospheric Pressure
Storage and Handling Type	Storage Environment Atmospheric Pressure
Storage and Handling Type	Storage Environment Humidity
Storage and Handling Type	Storage Environment Humidity
Storage and Handling Type	Storage Environment Temperature
Storage and Handling Type	Storage Environment Temperature
Storage and Handling Type	Handling Environment Atmospheric Pressure
Storage and Handling Type	Handling Environment Atmospheric Pressure
Storage and Handling Type	Handling Environment Humidity
Storage and Handling Type	Handling Environment Humidity
Storage and Handling Type	Handling Environment Temperature
Storage and Handling Type	Handling Environment Temperature
Support Contact Email	Use to provide the Contact Email for GUDID

GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
			used to sterilize the interiors of biological safety cabinets between uses.
Initial Manufacture Sterilization Initial Sterilization Prior to Use	GDSN Change Request (CR) in process to add this code value		
Storage and Handling GDSN Attributes	storageEnvironmentAtmosphericPressureMaximum		
Storage and Handling GDSN Attributes	storageEnvironmentAtmosphericPressureMinimum		
Storage and Handling GDSN Attributes	storageHandlingHumidityMaximum		
Storage and Handling GDSN Attributes	storageHandlingHumidityMinimum		
Storage and Handling GDSN Attributes	storageHandlingTemperatureMaximum		
Storage and Handling GDSN Attributes	storageHandlingTemperatureMinimum		
Storage and Handling GDSN Attributes	transportationEnvironmentAtmosphericPressureMaximum		
Storage and Handling GDSN Attributes	transportationEnvironmentAtmosphericPressureMinimum		
Storage and Handling GDSN Attributes	transportationMaximumHumidityMaximum		
Storage and Handling GDSN Attributes	transportationMaximumHumidityMinimum		
Storage and Handling GDSN Attributes	transportationMaximumTemperature		
Storage and Handling GDSN Attributes	transportationMinimumTemperature		
Communications Channel	EMAIL		N/A

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
Support Contact Phone	Use to provide the Contact Phone for GUDID	Communications Channel	TELEPHONE		N/A
UoM-	Pending	UoM- UN Recommendation 20	23	Grams Per Cubic Centimetre	Grams Per Cubic Centimetre
UoM-	Pending	UoM- UN Recommendation 20	59	Part per million	A unit of proportion equal to 10-6 (ppm).
UoM-	Pending	UoM- UN Recommendation 20	64	Pounds per square inch gauge	At sea level, Earth's atmosphere actually exerts a pressure of 14.7 psi. Humans do not feel this pressure because internal pressure of liquid in their bodies matches the external pressure. If a pressure gauge is calibrated to read zero in space, then at sea level on Earth it would read 14.7 psi. Thus a reading of 30 psig, on Earth, on a tire gauge represents an absolute pressure of 44.7 psi (lb/in^2).
UoM-	Pending	UoM- UN Recommendation 20	2Q	Kilo Becquerel	kBq is 10^3 Bq
UoM-	Pending	UoM- UN Recommendation 20	4N	Megabecquerel	106 Bq1 Bq is defined as the activity of a quantity of radioactive material in which one nucleus decays per second.
UoM-	Pending	UoM- UN Recommendation 20	A24	Candela per Square Meter	Candela per Square Meter is the SI base unit of luminous intensity that is, power emitted by a light source in a particular direction, weighted by the luminosity function in square meters. This is also known as nit in some markets.
UoM-	Pending	UoM- UN Recommendation 20	AIU	Anti XA Unit	A unit of measure for blood potency. Units for the anti XA activity which is a measure to the anti coagulating effect at low molecular heparins.
UoM-	Pending	UoM- UN Recommendation 20	AXU	Anti XA Unit (International Units)	A unit of measure for blood potency. International units for the anti XA activity which is a measure to the anti coagulating effect at low molecular heparins. A unit of measure for blood potency
UoM-	Pending	UoM- UN Recommendation 20	B10	Bit per second	In telecommunications and computing, bitrate (sometimes written bit rate, data rate or as a variable R or fb) is the number of bits that are conveyed or processed per unit of time. The bit rate is quantified using the bits per second (bit/s or bps) unit.

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
UoM-	Pending	UoM- UN Recommendation 20	B60	Lumens per Square Meter	
UoM-	Pending	UoM- UN Recommendation 20	B8	Board	
UoM-	Pending	UoM- UN Recommendation 20	BA	Bale	
UoM-	Pending	UoM- UN Recommendation 20	BD	Bundle	
UoM-	Pending	UoM- UN Recommendation 20	BG	Bag	
UoM-	Pending	UoM- UN Recommendation 20	BN	Bulk	
UoM-	Pending	UoM- UN Recommendation 20	BO	Bottle	
UoM-	Pending	UoM- UN Recommendation 20	BQ	Becquerel	The becquerel (symbol Bq) is the SI derived unit of radioactivity. One Bq is defined as the activity of a quantity of radioactive material in which one nucleus decays per second. SI uses the becquerel rather than the second for the unit of activity measure to avoid dangerous mistakes: a measurement in becquerels is proportional to activity, and thus a more dangerous source of radiation gives a higher reading. A measurement in seconds is inversely proportional.
UoM-	Pending	UoM- UN Recommendation 20	BQL	Becquerel	The becquerel (symbol Bq) is the SI derived unit of radioactivity. One Bq is defined as the activity of a quantity of radioactive material in which one nucleus decays per second. SI uses the becquerel rather than the second for the unit of activity measure to avoid dangerous mistakes: a measurement in becquerels is proportional to activity, and thus a more dangerous source of radiation gives a higher reading. A measurement in seconds is inversely proportional.
UoM-	Pending	UoM- UN Recommendation 20	BX	Box	
UoM-	Pending	UoM- UN Recommendation 20	C18	Millimole	a millimole is one thousandth of a mole.
UoM-	Pending	UoM- UN Recommendation 20	C34	Mole	The mole (symbol mol) is the SI base unit of amount of substance; one of a few units used to measure this

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
					physical quantity. A mole will possess mass exactly equal to the substance's molecular or atomic weight in grams. That is to say, a substance's atomic or molecular mass in atomic mass units is the same as its molar mass in grams. Because of this, one can measure the number of moles in a pure substance by weighing it and comparing the result to its molecular or atomic weight
UoM-	Pending	UoM- UN Recommendation 20	CA	Case	
UoM-	Pending	UoM- UN Recommendation 20	CN	Can	
UoM-	Pending	UoM- UN Recommendation 20	CQ	Cartridge	
UoM-	Pending	UoM- UN Recommendation 20	CT	Carton	
UoM-	Pending	UoM- UN Recommendation 20	CU	Cup	
UoM-	Pending	UoM- UN Recommendation 20	CV	Cover	
UoM-	Pending	UoM- UN Recommendation 20	D43	Atomic Mass Units (AMU)	Atomic Mass Units
UoM-	Pending	UoM- UN Recommendation 20	D70	Calorie - International Table (IT)	A calorie is 1/100 of the amount of energy required to warm one gram of air-free water from 0 °C to 100 °C at standard atmospheric pressure; this is about 4.190 J. Its use is archaic, having been replaced by the SI unit of energy, the joule. However, in many countries it remains in common use as a unit of food energy. In the context of nutrition, and especially food labelling, the calorie is approximately equal to 4.1868 joules (J), and energy values are normally quoted in kilojoules (kJ) and kilocalories (kcal).
UoM-	Pending	UoM- UN Recommendation 20	DO	Dollars, U.S.	
UoM-	Pending	UoM- UN Recommendation 20	DR	Drum	
UoM-	Pending	UoM- UN Recommendation 20	DRA	Dram (US)	The dram (archaic spelling drachm) was historically both a coin and a weight. Currently it is both a small mass in the Apothecaries' system of weights and a small unit of volume.

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
					This unit is called more correctly fluid dram or in contraction also fluidram. The term also refers to the fluid dram, a measure of capacity equal 1⁄8 of a fluid ounce, which means it is exactly equal to 3.696 691 195 312 5 mL in the United States.
UoM-	Pending	UoM- UN Recommendation 20	DRI	Dram (UK)	The dram (archaic spelling drachm) was historically both a coin and a weight. Currently it is both a small mass in the Apothecaries' system of weights and a small unit of volume. This unit is called more correctly fluid dram or in contraction also fluidram. The fluid dram is defined as 1⁄8 of a fluid ounce, which means it is exactly equal to 3.551 632 812 500 0 mL in the Commonwealth and Ireland. In England dram came to mean a small draught of cordial or alcohol; hence the term dram-house for the taverns where one could purchase a dram.
UoM-	Pending	UoM- UN Recommendation 20	DS	Display	
UoM-	Pending	UoM- UN Recommendation 20	E14	Kilocalorie (international table)	A unit of energy equal to 1000 calories.
UoM-	Pending	UoM- UN Recommendation 20	E37	Pixel	A unit of count defining the number of pixels (pixel: picture element).
UoM-	Pending	UoM- UN Recommendation 20	E39	Dots per inch	A unit of count defining the number of dots per linear inch as a measure of the resolution or sharpness of a graphic image.
UoM-	Pending	UoM- UN Recommendation 20	ELU	ELISA Units	Enzyme-linked immunosorbent assay unit, is always associated with a product and a method.
UoM-	Pending	UoM- UN Recommendation 20	EV	Envelope	
UoM-	Pending	UoM- UN Recommendation 20	FH	Micromole	One millionth (10 -6) of a mole.
UoM-	Pending	UoM- UN Recommendation 20	FJ	Sizing Factor	Commonly used to specify an order sizing factor related to a trade item to allow standard condition brackets for a variety of items. Different items or different configuration of an item may be assigned different points, e.g. an individual item may be a
UoM-	Pending	UoM- UN Recommendation 20	G24	Tablespoon	Tablespoon. 1/2 fluid ounces, 3 teaspoons, 15 millilitres

FDA GUDID Attribute	Code Value
UoM-	Pending
UoM-	Pending
UoM-	Pending
UoM-	Pending
UoM-	Pending
UoM-	Pending
UoM-	Pending
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UoM-	Pending
UoM-	Pending
UoM-	Pending

GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
UoM- UN Recommendation 20	G25	Teaspoon	Teaspoon. 1/6 fluid ounces or 5 millilitres
UoM- UN Recommendation 20	GBQ	Gigabecquerel	A unit of activity equal to 109 becquerels.
UoM- UN Recommendation 20	HEP	Histamine Equivalent Prick	Histamine equivalent prick testing for allergen.
UoM- UN Recommendation 20	HL	Hundred Feet	
UoM- UN Recommendation 20	JR	Jar	
UoM- UN Recommendation 20	KE	Keg	
UoM- UN Recommendation 20	KEL	Kelvin	Kelvin: a unit of absolute temperature equal to 1/273.16 of the absolute temperature of the triple point of water. One kelvin degree is equal to one Celsius degree.
UoM- UN Recommendation 20	KIU	Kallikrein inactivator unit.	Kallikrein Inactivator Unit per Milliliter definition: An arbitrary unit of a kallikrein inactivator concentration equal to the concentration at which one milliliter of the mixture contains one unit of the kallikrein inactivator
UoM- UN Recommendation 20	KO	Milliequivalence caustic potash per gram of product	A unit of count defining the number of milligrams of potassium hydroxide per gram of product as a measure of the concentration of potassium hydroxide in the product.
UoM- UN Recommendation 20	LUX	Lux	Lux is the SI unit of illuminance and luminous emittance, measuring luminous flux per unit area.
UoM- UN Recommendation 20	MEQ	mEq or milliequivalents	Milliequivalents of solute per liter of solvent (or milliNormal where mEq/L = mN). This is especially common for measurement of compounds in biological fluids for instance, the healthy level of potassium in the blood of a human is defined between 3.5 and 5.0 mEq/L.
UoM- UN Recommendation 20	MIU	Million International Unit (NIE)	A unit of count defining the number of international units in multiples of 106.
UoM- UN Recommendation 20	MX	Mod Pallet (Mixed)	
UoM- UN Recommendation 20	ON	Ounces per square yard	The weight of one square yard of the material expressed in ounces. Commonly used to express the density or weight of all types of paper, paperboard, and fabric, e.g. 20 OZ or 20 Weight denim has an area density

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
					of 20 oz/yd2. The term density here is used somewhat incorrectly, as density is mass by volume. More precisely, it is a measure of the area density, areal density, or surface density.
UoM-	Pending	UoM- UN Recommendation 20	PE	Pounds Equivalent	
UoM-	Pending	UoM- UN Recommendation 20	PFU	Plaque Forming unit(s)	Plaque Forming unit(s)
UoM-	Pending	UoM- UN Recommendation 20	PK	Package	
UoM-	Pending	UoM- UN Recommendation 20	PRS	Potential Renal Solute Load	Refers to all solutes of endogenous or dietary origin that require excretion by the kidneys. Potential renal solute load (PRSL) refers to solutes of dietary origin that would need to be excreted in the urine if none were diverted into synthesis of new tissue and none were lost through nonrenal routes. This is very important to be able to transmit for infant formulas.
UoM-	Pending	UoM- UN Recommendation 20	PTN	Portion	
UoM-	Pending	UoM- UN Recommendation 20	RL	Roll	
UoM-	Pending	UoM- UN Recommendation 20	SH	Sheet	
UoM-	Pending	UoM- UN Recommendation 20	SQE	SQ-E	Number of allergens based on the SQ-E unit
UoM-	Pending	UoM- UN Recommendation 20	TE	Tote	
UoM-	Pending	UoM- UN Recommendation 20	TK	Tank	
UoM-	Pending	UoM- UN Recommendation 20	TM	Thousand Feet	
UoM-	Pending	UoM- UN Recommendation 20	TY	Tray	
UoM-	Pending	UoM- UN Recommendation 20	UY	Fifty Square Feet	
UoM-	Pending	UoM- UN Recommendation 20	UZ	Fifty Count	
UoM-	Pending	UoM- UN Recommendation 20	V2	Pouch	
UoM-	Pending	UoM- UN Recommendation 20	X_CHD	Centisimal Hahnemannian Dilution (CH)	A count of attenuation steps or dilution levels representing the homeopathic potency of a substance using the Hahnemannian (CH) method of attenuation; commonly denoted as CH1, CH2, CH3, etc.

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
					Each centesimal attenuation step represents one part source material combined with 99 parts dilution medium; commonly denoted as C1, C2, C3, etc.
UoM-	Pending	UoM- UN Recommendation 20	X_KVN	Korsakovian (K)	A count of attenuation steps or dilution levels representing the homeopathic potency of a substance using the Korsakovian (K) method of attenuation; commonly denoted as CK1, CK2, CK3, etc. Each centesimal attenuation step represents one part source material combined with 99 parts dilution medium; commonly denoted as C1, C2, C3, etc.
UoM-	Pending	UoM- UN Recommendation 20	X_MLM	Millesimai (LM)	A count of attenuation steps or dilution levels representing the homeopathic potency of a substance where each attenuation step represents one part source material combined with 49,999 parts dilution medium; commonly denoted as LM1, LM2, LM3, etc.
UoM-	Pending	UoM- UN Recommendation 20	X_MTC	Mother tincture (Dry material)	A count of a dry crud medical substance Mother tincture, when used for homeopathic preparations, are liquid preparations obtained by the solvent action of a suitable vehicle upon raw materials. The raw materials (medical substance) are usually in the fresh form but may be dried. Mother tinctures for homeopathic preparations may also be obtained from plant juices, with, or without the addition of a vehicle.
UoM-	Pending	UoM- UN Recommendation 20	X_NGM	Nanogram	A nano gram is 10-9 gram or a billionth of a gram..
UoM-	Pending	UoM- UN Recommendation 20	X_PPC	Pixel per centimetre	A unit of count defining the number of pixels per linear centimetre as a measurement of the resolution of devices in various contexts; typically computer displays, image scanners or digital camera image sensors.
UoM-	Pending	UoM- UN Recommendation 20	X_PPI	Pixel per inch	A unit of count defining the number of pixels per linear inch (PPI) as a measurement of the resolution of devices in various contexts; typically computer displays, image scanners or digital camera image sensors.

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
UoM-	Pending	UoM- UN Recommendation 20	X_SPS	Sample per second	A unit of count defining the number of samplings takes during a period of time
UoM- Size Unit of Measure	Pending	UoM- UN Recommendation 20	4H	Micrometre	A micrometre is one millionth of a metre, also termed Micron.
UoM- Size Unit of Measure	Pending	UoM- UN Recommendation 20	H79	French gauge	The French scale (most correctly abbreviated as Fr, but also often abbreviated as FR or F) is commonly used to measure the catheter size (Circumference is in millimeters), in which 1 Fr = 0.33 mm in diameter. In the French Gauge system as it is also known, the diameter in millimeters of the catheter can be determined by dividing the French size by 3, thus an increasing French size corresponds with a larger diameter catheter. The following equations summarize the relationships: D(mm) = Fr/3 or Fr = D(mm)*3
UoM- Size Unit of Measure	Pending	UoM- UN Recommendation 20	PNT	Point	A single unit on a scale of measurement as part of an incentive program or pricing structure used as a means of making a quantitative evaluation.
UoM- Storage and Handling Type\Unit of Measure	Pending	UoM- UN Recommendation 20	80	Pound per square inch - Absolute	Psia (pound-force per square inch absolute)is a unit of pressure pressure relative to a vacuum (such as that in space). At sea level, Earth's atmosphere actually exerts a pressure of 14.7 psi. Humans do not feel this pressure because internal pressure of liquid in their bodies matches the external pressure. If a pressure gauge is calibrated to read zero in space, then at sea level on Earth it would read 14.7 psi. Thus a reading of 30 psig, on Earth, on a tire gauge represents an absolute pressure of 44.7 psi (lb/in^2).
UoM- Storage and Handling Type\Unit of Measure	Pending	UoM- UN Recommendation 20	PAL	Pascal	The pascal (symbol: Pa) is the SI derived unit of pressure, stress, Young's modulus and tensile strength. It is a measure of force per unit area, defined as one newton per square metre.
UoM- Storage and Handling Type\Unit of Measure	Pending	UoM- UN Recommendation 20	PS	Pound-force per square inch	The pound-force per square inch (symbol: psi or lbf/in2 or lbf/in2) is a unit of pressure or of stress based on avoirdupois units. It is the pressure

FDA GUDID Attribute	Code Value	GS1 GDSN Attribute	Code Value	Description (where needed)	Definition
					resulting from a force of one pound-force applied to an area of one square inch. Other abbreviations are used that append a modifier to "psi". However, the US National Institute of Standards and Technology recommends that, to avoid confusion, any modifiers be instead applied to the quantity being measured rather than the unit of measure[1] For example, "Pg = 100 psi" rather than "P = 100 psig".

6. Guidance on populating values

This section provides guidance on how to populate each of the GS1 GDSN attributes to meet the requirements of the FDA GUDID attribute list. The choice of attributes in this guidance is related to the GUDID to GDSN Mapping provided in section 4. The guidance is ordered according in line with the order as presented from the FDA documentation.

1. Issuing Agency

FDA GUDID

Description - Organization accredited by FDA to operate a system for the issuance of UDIs.

Data Entry Notes	Choose a value from the drop down list (Webtool)
Edit Rules After Grace Period	Cannot edit, add or delete after the Grace Period
Required?	1..1 Required
Data Type & Length	Alphanumeric, 30
Entry List of Values (LOV)	GS1, HIBCC, ICCBBA
New DI Trigger?	YES
Public/Private Status	PUBLIC

GS1 GDSN

Attribute Name	N/A- LOGICAL POPUALTION
Definition	N/A
Data Type	N/A
GDSN Required	N/A

Population Guidance (below)

LOGICAL POPULATION - On the outbound GUDID Message by the Data Pool. Will use the value "GS1" in all GDSN instances. By using GDSN, the GTIN of the lowest level of the hierarchy will become the Primary DI. By using a GTIN as the Primary DI, this will require the issuing agency to be GS1.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be changed. Many of the data elements are locked and can no longer be edited.

2. Primary DI#

FDA GUDID

Description – An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest level of a medical device containing a full UDI.

Data Entry Notes	GS1- 14-digit numeric value, HIBCC - 6-23 character alphanumeric value, ICCBBA- 10 or 16 character alphanumeric value
Edit Rules After Grace Period	Cannot edit, add, or delete after Grace Period.

Required?	1..1, Required
Data Type & Length	Numeric or Alphanumeric characters, 6-23 characters
Entry List of Values (LOV)	N/A
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Attribute Name	globalTradeItemNumber

Definition - A particular Global trade item Number, a numerical value used to uniquely identify a trade item. A trade item is any trade item (trade item or service) upon which there is a need to retrieve pre-defined information and that may be planned, priced, ordered, delivered and or invoiced at any point in any supply chain.

Data Type	Identifier (14 digits)
GDSN Required	MANDATORY

Population Guidance (below)

This is one of the key elements in GDSN and is required for the use of GDSN. By using GDSN to provide data to the GUDID, the GTIN will always be the Primary DI. All other issuing agency identification will be published as secondary.

Once published, a 7-day grace period begins. During the grace period, most attribute can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

3. Device Count

FDA GUDID

Description – Number of medical devices in the base package. For example, Base Package = Box of 100 gloves; Primary DI = 101; Device Count = 100.

Data Entry Notes	Enter a numeric value.
Edit Rules After Grace Period	Cannot edit, add, or delete after Grace Period.
Required?	1..1, Required
Data Type & Length	Numeric, 7
Entry List of Values (LOV)	N/A
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Attribute Name	Net Content & UoM

Definition - The amount of the trade item contained by a package, usually as claimed on the label. For example, Water 750ml - net content = "750 MLT" ; 20 count pack of diapers, net content = "20 ea.". In case of multi-pack, indicates the net content of the total trade item. For fixed value trade items use the value claimed on the package, to avoid variable fill rate issue that arises with some

trade item which are sold by volume or weight, and whose actual content may vary slightly from batch to batch. In case of variable quantity trade items, indicates the average quantity.

Data Type	Numeric + Code List
GDSN Required	N/A

Population Guidance (below)

The net content attribute is a measurement attribute which is a number and a corresponding qualifier representing the unit of measure (UoM). The unit of measure code values are from the United Nations Recommendation 20 Code List (UN Rec 20).

For GDSN, net content is required when the attribute is trade item a consumer unit is populated with a value of TRUE. This attribute refers to if an item is the unit of end consumption.

It is important to note that if the Device Count is greater than 1 (>1), then a Unit of Use DI is required to be provided in the GUDID.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

4. Unit of Use DI# Number

FDA GUDID

Description – An identifier assigned to an individual medical device when a UDI is not labelled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.

Data Entry Notes – GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value If Device Count =1, cannot add Unit of Use DI Number.

Edit Rules After Grace Period	Can edit after Grace Period if Device Count > 1.
Required?	0..* Required if device count is greater than one
Data Type & Length	Numeric or Alphanumeric, 6-23 characters
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1GDSN

Attribute Name	FDA Unit Of Use GTIN

Definition - GTIN of a unit of use, as defined by the FDA. This is a lower level unit which is contained in the Trade Item.

Data Type	GTIN
GDSN Required	N/A

Population Guidance (below)

If the Device Count is greater than 1 (>1), the unit of use DI# is required for population in the GUDID.

This attribute is a temporary attribute (AVP) in GDSN. It will be deployed into the GDSN Schema in 2016-17 into a final solution. This final solution will be part of the GDSN solution for “Level below Each” (LBE).

5. Labeler DUNS Number

FDA GUDID

Description – Business number issued by Dun & Bradstreet (D&B) that matches the Labeler (Company) name on device label.

Data Entry Notes – Choose appropriate DUNS Number from drop down. Choose appropriate DUNS Number from drop down. (Webtool)

Edit Rules After Grace Period	Can edit after Grace Period.
Required?	1..1, Required
Data Type & Length	Numeric, 9
Entry List of Values (LOV)	from DUNS
New DI Trigger?	NO
Public/Private Status	Private

GS1 GDSN

Attribute Name — Pair of attributes in combination

a. additionalPartyIdentification\type

b. additionalPartyIdentification\value

Definition

a. Identification of a party by use of a code other than the Global Location Number.

b. A party identifier that is in addition to the GLN.

Data Type

a. Code List (Multiple Occurrence)

b. Text (Multiple Occurrence)

GDSN Required – OPTIONAL, however if one of the pair of attributes is populated both attributes must be populated.

Population Guidance (below)

The GUDID is asking for a DUNS number for the Labeler. This value will be for the Company as listed on the label. For GDSN, the Labeler is equivalent to the Brand Owner.

Population of this value can be accomplished by populating the code values “DUNS” or “DUNS_PLUS_FOUR” in the GDSN attribute Additional Party Identification\type tied to the attribute Brand Owner GLN. The actual “DUNS” or “DUNS_PLUS_FOUR” number can then populated in the GDSN attribute Additional Party Identification\value. The number populated in Additional Party Identification\value will be populated in GUDID as the Labeler DUNS Number.

6. Company Name

FDA GUDID

Description – Company name associated with the Labeler DUNS Number entered in the DI Record. This name should match the company name on the device label.

Data Entry Notes	System Populated

Edit Rules After Grace Period	Can be edited through D&B only.
Required?	1..1, Required
Data Type & Length	Alphanumeric
Entry List of Values (LOV)	N/A
New DI Trigger?	N/A
Public/Private Status	Public

GS1 GDSN

Attribute Name	N/A
Definition	N/A
Data Type	N/A
GDSN Required	N/A

Population Guidance (below)

The FDA will populate this information into the GUDID based on information from D&B based on the Labeler DUNS # provided. If the information is not correct, D&B should be contacted to facilitate correcting the data.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can only be changed with Dunn and Bradstreet (D&B). Many of the data elements are locked and can no longer be edited.

7. Company Physical Address

FDA GUDID

Description – Company physical address associated with the DUNS Number entered in the DI. This address should match the address on the device label.

Data Entry Notes	System Populated
Edit Rules After Grace Period	Can be edited through D&B only.
Required?	1..1, Required
Data Type & Length	Alphanumeric
Entry List of Values (LOV)	N/A
New DI Trigger?	N/A
Public/Private Status	Private

GS1 GDSN

Attribute Name	N/A
Definition	N/A
Data Type	N/A
GDSN Required	N/A

Population Guidance (Below)

The FDA will populate this information into the GUDID based on information from D&B based on the Labeler DUNS # provided. If the information is not correct, D&B should be contacted to facilitate correcting the data.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can only be changed with Dunn and Bradstreet (D&B). Many of the data elements are locked and can no longer be edited.

8. Brand Name

FDA GUDID

Description – The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand name is the name that is typically registered with USPTO and have the ® and/or TM symbol.

Data Entry Notes – Enter the name of the device. Only the ® and ™ symbols will be supported for the production release.

Edit Rules After Grace Period	Cannot edit after Grace Period.
Required?	1..1, Required
Data Type & Length	Alphanumeric and symbols, 80
Entry List of Values (LOV)	N/A
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Attribute Name	brandName

Definition -The recognisable name used by a brand owner to uniquely identify a line of trade item or services. This is recognizable by the consumer.

Data Type	Text (1-35 characters)
GDSN Required	MANDATORY

Population Guidance (below)

This should be the most recognizable brand on the package/trade item. If there is no brand on the package/trade item, this should be the brand name under which the item is sold.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be changed. Many of the data elements are locked and can no longer be edited.

9. Version or Model Number

FDA GUDID

Description - The version or model number found on the device label or accompanying packaging used to identify a category or design of a device. The version or model means all devices that have specifications, performance, size, and composition, within limits set by labeler.

Data Entry Notes	Enter an alphanumeric value.

Edit Rules After Grace Period	Cannot edit after Grace Period.
Required?	1..1 Required
Data Type & Length	Alphanumeric and symbols, 40
Entry List of Values (LOV)	N/A
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Attribute Name	Pair of attributes in combination

a. additionalTradeItemIdentificaton\type

b. additionalTradeItemIdentificaton\value

Definition-

a. Type of the identification system that is being used as an alternative to the Global Trade Item Number.

b. Alternative means to the Global Trade Item Number to identify a trade item.

Data Type

a. Code List (Multiple Occurrence)

b. Text (Multiple Occurrence)

GDSN Required – OPTIONAL, however if one of the pair is populated the other must be populated.

Population Guidance (below)

The GUDID is asking for a Model Number for the device. This can be accomplished by the population of the code value “MODEL_NUMBER” in the GDSN attribute additionalPartyIdentification/type. The actual Model Number can then be populated in the GUDID using the associated additionalPartyIdentification\value(s).

The code value of MODEL_NUMBER is defined as- (Definition for GDSN Major Release 3.x in 2016) - The additional Trade Item Identification value populated is an identification number, which defines the configuration of the product in addition to the Item number. This is typically printed or otherwise attached to an item. In electronics, this number is typically found around or near a serial number.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be changed. Many of the data elements are locked and can no longer be edited.

10. Catalog Number

FDA GUDID

Description – The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.

Data Entry Notes	Enter an alphanumeric value. No symbols are accepted.
Edit Rules After Grace Period	Can edit after Grace Period.
Required?	0..1 Not Required

Data Type & Length	Alphanumeric and symbols, 40
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name Pair of attributes in combination

a. additionalTradeItemIdentificaton\type

b. additionalTradeItemIdentificaton\value

Definition

a. Type of the identification system that is being used as an alternative to the Global Trade Item Number.

b. Alternative means to the Global Trade Item Number to identify a trade item.

Data Type

a. Code List (Multiple Occurrence)

b. Text (Multiple Occurrence)

GDSN Required OPTIONAL, however if one of the pair is populated the other must be populated.

Population Guidance (below)

The GUDID is asking for a Model Number for the device. This can be accomplished by the population of the code value "SUPPLIER_ASSIGNED" in the GDSN attribute additionalPartyIdentification/type. The actual Model Number can then be populated in the GUDID using the associated additionalPartyIdentification\value(s).

The code value of SUPPLIER_ASSIGNED is defined as- (Definition for GDSN Major Release 3.x in 2016)- The additional Trade Item Identification value populated has been developed and assigned by the party which provides service(s) and/or manufactures or otherwise has possession of the goods and consigns or makes them available in trade. This number is a base model or style number assigned to the product and may be the same for several GTINs where they are variations of each other. For example a coffee mug with 3 GTINs one each for the brown mug, the white mug, and the black mug might all be the supplier assigned number of AB123. Use of this value is recommended in the absence of a Model Number or Manufacturer's Part Number.

11. Device Description (max 2000 characters)

FDA GUDID

Description – Additional relevant information about the device that is not already captured as a distinct GUDID data attribute.

Data Entry Notes - Enter device description. Only the ® and ™ symbols will be supported for the production release

Edit Rules After Grace Period	Can edit, add, or delete after Grace Period.
Required?	0..1, Not Required
Data Type & Length	Alphanumeric and symbols, 2000
Entry List of Values (LOV)	N/A

New DI Trigger? NO

Public/Private Status Public

GS1 GDSN

Attribute Name- Pair of attributes in combination

a. Trade Item Description

b. Additional Trade Item Description\text

Definition

An understandable and useable description of a trade item using brand and other descriptors. This attribute is filled with as little abbreviation as possible while keeping to a reasonable length. Free form text field, this data element is repeatable for each language used and must be associated with a valid ISO language code. Field length is 178 characters. This should be a meaningful description of the trade item with full spelling to facilitate message processing. Retailers can use this description as the base to fully understand the brand, flavour, scent etc. of the specific GTIN in order to accurately create a product description as needed for their internal systems. Examples:

1. GS1 Brand Base Invisible Solid Deodorant AP Stick Spring Breeze
2. GS1 Brand Laundry Detergent Liquid Compact Regular Instant Stain 1
3. GS1 Brand Hair Colour Liquid Light to Medium Blonde

b. Additional variants necessary to communicate to the industry to help define the product. Multiple variants can be established for each GTIN.

Data Type

a. Text (Language Qualifier) (1 to 178 Characters)

b. Text (1-350 characters)

GDSN Required OPTIONAL

Population Guidance (below)

These two attributes will be concatenated together into one value when provided to the GUDID. The concatenation of these two descriptions will provide the best description available as some labellers might have used only one of the two fields. If only one of the attributes is populated in GDSN, only that value will be populated in the GUDID.

12. DI Record Publish Date (mm/dd/yyyy)

FDA GUDID

Description – Indicates the date the DI Record gets published and is available via Public Search.

Data Entry Notes – Choose date from calendar or manually enter in format (mm/dd/yyyy) (Drop down is for Webtool only)

Edit Rules After Grace Period Cannot edit, add, or delete after Published.

Required? 1..1, Required

Data Type & Length Numeric date format, 10

Entry List of Values (LOV) N/A

New DI Trigger? NO

Public/Private Status Public

GS1 GDSN

Attribute Name	effectiveDate

Definition- The date on which the information contents of the master data version are valid. Valid = correct or true. This effective date can be used for initial trade item offering, or to mark a change in the in-formation related to an existing trade item. This date would mark when these changes take effect.

Data Type	Date Time (CCYY-MM-DDTHH:MM:SS)
GDSN Required	MANDATORY

Population Guidance (below)

For GDSN, most data pools will auto-populate this date for the manufacturer. However, if a date is populated, that date will not be overwritten.

The Labeler will need to pay particular attention to this date. On this date, the device information will be published by the FDA to the public GUDID site. Once published, a 7-day grace period begins. Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

13. Commercial Distribution End Date (mm/dd/yyyy)

FDA GUDID

Description – Indicates the date the device is no longer held or offered for sale. See 21 CFR 807.3(b) for exceptions. The device may or may not still be available for purchase in the marketplace.

Data Entry Notes - Choose date from calendar or manually enter in format (mm/dd/yyyy). (Drop down is for Webtool only)

Edit Rules After Grace Period	Can edit, add, or delete after Grace Period.
Required?	0..1, Not Required
Data Type & Length	Numeric date format, 10
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	lastShipDate

Definition - Indicates the latest date that the trade item can be shipped. This is independent of any specific ship-from location.

Data Type	Date Time (CCYY-MM-DDTHH:MM:SS)
GDSN Required	OPTIONAL

Population Guidance (below)

This date signals that a trade item will no longer be in distribution from the Labeler.

14. Commercial Distribution Status

FDA GUDID

Description – Indicates whether the device is in commercial distribution as defined under 21 CFR 807.3(b).

Data Entry Notes	System Populated
Edit Rules After Grace Period	N/A
Required?	0..1, Required if record is published
Data Type & Length	N/A
Entry List of Values (LOV)	In Commercial Distribution; Not in Commercial Distribution
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	Derived by the FDA GUDID based on effectiveDate and lastShipDate
Definition	N/A
Data Type	N/A
GDSN Required	N/A

Population Guidance (below)

If the current date is equal to or greater than the GUDID Publication Date (effectiveDate in GDSN), then the Commercial Distribution Status will be set to “In Commercial Distribution” automatically by the FDA. If the current date is equal to or greater than the GUDID Commercial Distribution End Date (lastShipDate in GDSN), then the Commercial Distribution Status will be set to “Not in Commercial Distribution” automatically by the FDA.

15. Device Subject to Direct Marking (DM), but Exempt

FDA GUDID

Description – The device is exempt from Direct Marking requirements under 21 CFR 801.45.

Data Entry Notes	Select checkbox if appropriate. (Webtool)
Edit Rules After Grace Period	Can add or delete after Grace Period.
Required?	O..1 Not Required
Data Type & Length	Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Temporary population until final GDSN deployment-

isTradeItemExemptFromDirectPartMarking

Definition- Indicator signifying the trade item is exempt from direct identification marking according to regulation or regulatory filings within the target market.

Data Type	Boolean
GDSN Required	Optional
Final Deployment Attribute Name	isTradeItemExemptFromDirectPartMarking

Definition- Indicator signifying the trade item is exempt from direct identification marking according to regulation or regulatory filings within the target market.

Data Type	Boolean
GDSN Required	Optional

Population Guidance (below)

This value should default to FALSE, unless a Labeler has an exemption and specifically changes the flag to TRUE.

This attribute is a temporary attribute (AVP) in GDSN. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

16. DPM DI Different from Primary DI

FDA GUDID

Description – Indicates that the DM DI Number is different than the Primary DI Number.

Data Entry Notes	Select checkbox if appropriate. (WebTool)
Edit Rules After Grace Period	Can add or delete after Grace Period.
Required?	0..1 Not Required
Data Type & Length	Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	N/A
Definition	N/A
Data Type	N/A
GDSN Required	N/A

Population Guidance (below)

LOGICAL POPULATION- (Logical BOOLEAN value of “TRUE” from the population of a value of “DIRECT_PART_MARKING” in GDSN Attribute additionalTradeItemIdentification\type). This GUDID attribute is a Boolean and as such requires a “TRUE” or “FALSE” flag as a value. If there is a value populated for the GDSN attribute combination of additionalTradeItemIdentificaton\type of “DIRECT_PART_MARK”, and an associated additionalTradeItemIdentificaton\value, then the logical value for the GUDID is “TRUE”, else this value is “FALSE”.

17. DPM DI Number

FDA GUDID

Description – An identifier that is marked directly on the medical device and is different than the Primary DI Number; only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45.

Data Entry Notes GS1- 14-digit numeric value, HIBCC - 6-23 character alphanumeric value, ICCBBA- 10 or 16 character alphanumeric value

Edit Rules After Grace Period Can edit, add, or delete after Grace Period.

Required? 0..* Required only if check box for 'DM DI Different from Primary DI'

Data Type & Length Numeric or Alphanumeric, 6-23 characters

Entry List of Values (LOV) N/A

New DI Trigger? NO

Public/Private Status Public

GS1 GDSN

Temporary population until final GDSN deployment - directPartMarking

Definition This is a number or marking placed directly on the medical device.

Data Type Text

GDSN Required Optional

Final Deployment Attribute Name Pair of attributes in combination

additionalTradeItemIdentificaton\type

additionalTradeItemIdentificaton\value

Definition

a. Type of the identification system that is being used as an alternative to the Global Trade Item Number.
b. Alternative means to the Global Trade Item Number to identify a trade item.

Data Type

a. Code List (Multiple Occurrence)
b. Text (Multiple Occurrence)

GDSN Required OPTIONAL, however if one is populated the other must also be populated.

Population Guidance (below)

This should only be populated if:

a) there is a Direct Part Mark on the Device

AND

b) the DI# used in the Direct Part Mark is **NOT** the Primary DI#

This attribute has a temporary attribute (AVP) in GDSN- directPartMarking. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

Population of the GDSN Attribute additionalTradeItemIdentificaton\type with a value of “DIRECT_PART_MARK” will allow for the appropriate additionalTradeItemIdentificaton\value to be

populated. This attribute pair can be repeated for as many DPM DI#s the item might have. The value populated in the GDSN attribute additionalTradeItemIdentificaton\type attribute associated with the additionalTradeItemIdentificaton\value ("DIRECT_PART_MARK") is what will be populated in the GUDID.

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Version or Model Number, Catalog Number, Secondary DI Number, and FDA Listing Number.

18. Secondary DI Issuing Agency

FDA GUDID

Description	Name of Secondary DI Issuing agency.
Data Entry Notes	Choose from drop down. (Webtool)
Edit Rules After Grace Period	Cannot edit, add or delete after Grace Period
Required?	1..* Required if there is a Secondary DI Number
Data Type & Length	Alphanumeric, 30
Entry List of Values (LOV)	GS1; HIBCC; ICCBBA; NHRIC
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	additionalTradeItemIdentificaton\type

Definition

Type of the identification system that is being used as an alternative to the Global Trade Item Number.

Data Type	Code List
GDSN Required	OPTIONAL (Multiple Occurrence)

Population Guidance (below)

The GS1 General Specifications stipulate that a Trade Item can only have one GTIN. As the GTIN is the primary DI# for an item using GDSN to provide data to the GUDID, a GTIN using GS1 as the issuing agency can not be a secondary DI#. However, the item might have another issuing agency's item number standard in use. Using the GDSN attribute, additionalTradeItemIdentificaton\type, these other issuing agency identifiers can be provided. Currently, the GDSN attribute has code values for other issuing agencies which would have an associated additionalTradeItemIdentificaton\value provided to the GUDID. If a value is populated through GDSN for an issuing agency using the attribute additionalTradeItemIdentificaton\type it will be provided to the GUDID as a secondary DI. The codes available for the Secondary DI Issuing Agency are "HIBC", and "ICCBBA". The population of one of these additionalTradeItemIdentificaton\type values will denote the appropriate issuing agency code value for GUDID.

This attribute is required if a value is populated for additionalTradeItemIdentificaton\value.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Version or Model Number, Catalog Number, Secondary DI Number, and FDA Listing Number.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

19. Secondary DI Number

FDA GUDID

Description – An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI.

Data Entry Notes – GS1- 14- digit numeric value, HIBCC - 6-23 character alphanumeric value, ICCBBA- 10 or 16 character alphanumeric value, NHRIC- 10-digit numeric value.

Edit Rules After Grace Period	Cannot edit, add or delete after Grace Period
Required?	1..* Required if there is a Secondary DI Number
Data Type & Length	Numeric or Alphanumeric, 6-23 characters
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	additionalTradeItemIdentificaton\value
Definition	
Data Type	Text
GDSN Required	OPTIONAL (Multiple Occurrence)
Population Guidance	

The GS1 General Specifications stipulate that a Trade Item can only have one GTIN. As the GTIN is the primary DI# for an item using GDSN to provide data to the GUDID, a GTIN using GS1 as the issuing agency can not be a secondary DI#. However, the item might have another issuing agency's item number standard in use. Using the GDSN attribute, additionalTradeItemIdentificaton\value, these other issuing agency identifiers can be provided. If a value is populated through GDSN for an issuing agency using the attribute additionalTradeItemIdentificaton\type it will be provided to the GUDID as a secondary DI. The population of one of the additionalTradeItemIdentificaton\type values for an issuing agency will denote the appropriate issuing agency code value for GUDID for which the value populated in this attribute is relevant.

This attribute is required if a value is populated for additionalTradeItemIdentificaton\type.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Version or Model Number, Catalog Number, Secondary DI Number, and FDA Listing Number.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

20. Package DI Number

FDA GUDID

Description – A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers). For example:

4 glove boxes in a Carton -- Package DI =201 (the UDI on the Carton)

5 Cartons in a Case -- Package DI=301 (the UDI on the Case)

contains a 5 cartons (with DI 201) with 4 glove boxes in a carton

10 glove boxes in a Carton -- Package DI=202 (the UDI on the Carton).

Data Entry Notes GS1- 14-digit numeric value, HIBCC - 6-23 character alphanumeric value, ICCBBA- 10 or 16 character alphanumeric value

Edit Rules After Grace Period	Can add after Grace Period, but cannot delete.
Required?	0..* Not Required, Required if Package Configuration is entered
Data Type & Length	Alphanumeric, 6-23 depending on Issuing Agency
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name - globalTradeItemNumber (hierarchy levels where isTradeItemABaseUnit is FALSE)

Definition - A particular Global trade item Number, a numerical value used to uniquely identify a trade item. A trade item is any trade item (trade item or service) upon which there is a need to retrieve pre-defined information and that may be planned, priced, ordered, delivered and or invoiced at any point in any supply chain.

Data Type Identifier (14 digits)

GDSN Required- DEPENDENT (not populated where isTradeItemABaseUnit is TRUE)

Population Guidance (below)

The GUDID Package attributes are populated as a group and can not be entered as single elements in the message. These attributes are:

- Package DI Number
- Quantity per Package
- Contains DI Package
- Package Type
- Package Discontinue Date

All packages must be entered. If a new package level is created, it is to be added to the GUDID as part of the Primary DI to which it is applicable.

This GDSN attribute references a GTIN in the hierarchy above the primary DI. This would be, or is one of, the “parent(s)” of the primary DI. See the example below.

In GDSN, the following is provided.

Hierarchy Number 1

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
2061414111111c	CASE	1061414111111c	5	5 cartons in a case
1061414111111c	PACK_OR_INNER_PACK	0061414111111c	4	4 boxes in a carton
0061414111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

Hierarchy Number 2

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
4061414111111c	CASE	3061414111111c	2	2 cartons in a case
3061414111111c	PACK_OR_INNER_PACK	0061414111111c	10	10 boxes in a carton
0061414111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

This is converted to the following for population in the GUDID.

Package DI Number	Quantity per package	Contains DI Package	Notes
1061414111111c	4	0061414111111c	Indicates there are 4 eaches in the pack
2061414111111c	5	3061414111111c	Indicates there are 5 packs in the case
3061414111111c	10	0061414111111c	Indicates there are 10 eaches in the pack
4061414111111c	2	3061414111111c	Indicates there are 2 packs in the case

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be deleted.

21. Quantity per package

FDA GUDID

Description – The number of packages with a unique primary DI within a given packaging configuration. For example:

Package configuration Carton with Package DI=201 contains 4 boxes of the base package DI=101, the quantity per package is 4;

Package configuration Case with Package DI=301 contains 5 cartons of Package DI=201, the quantity per package is 5.

Package configuration Carton with Package DI=202 contains 10 boxes of the base package DI=101; the quantity per package is 10.

Data Entry Notes- The quantity of a package configuration needs to be greater than 1.

Edit Rules After Grace Period - Can add with new package configuration after Grace Period, but cannot delete

Required?	0..* Required if Package Configuration is entered
Data Type & Length	Numeric, 9
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	quantityofNextLowerLevelTradeItem

Definition – The number of one child trade item (as identified by the association of ChildTradeItem class to TradeItemIdentification class) contained by the parent trade item. The child trade item must be in the hierarchy level immediately below the parent trade item.

Data Type	Integer
GDSN Required	DEPENDENT (not populated where isTradeItemABaseUnit is TRUE)

Population Guidance (below)

The GUDID Package attributes are populated as a group and can not be entered as single elements in the message. These attributes are:

- Package DI Number
- Quantity per Package
- Contains DI Package
- Package Type
- Package Discontinue Date

All packages must be entered. If a new package level is created, it is to be added to the GUDID as part of the Primary DI to which it is applicable.

This GDSN attribute references the quantity of the child trade item (GUDID- Contains DI Package), which is contained in the GTIN (GUDID- Package DI Number). See the example below.

In GDSN, the following is provided.

Hierarchy Number 1

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
2061414111111c	CASE	1061414111111c	5	5 cartons in a case
1061414111111c	PACK_OR_INNER_PACK	0061414111111c	4	4 boxes in a carton

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
00614141111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

Hierarchy Number 2

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
40614141111111c	CASE	30614141111111c	2	2 cartons in a case
30614141111111c	PACK_OR_INNER_PACK	00614141111111c	10	10 boxes in a carton
00614141111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

This is converted to the following for population in the GUDID.

Package DI Number	Quantity per package	Contains DI Package	Notes
10614141111111c	4	00614141111111c	Indicates there are 4 eaches in the pack
20614141111111c	5	30614141111111c	Indicates there are 5 packs in the case
30614141111111c	10	00614141111111c	Indicates there are 10 eaches in the pack
40614141111111c	2	30614141111111c	Indicates there are 2 packs in the case

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be deleted.

Contains DI Package

FDA GUDID

Description – The primary DI for the base package or any lower level package configuration contained within a given package configuration. For example:

Package DI=201 and Package DI=202 contain the base package Case with primary DI=101;

Package DI=301 contains lower level package configuration of a Carton with Package DI=201.

Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period but cannot delete	Can add with new package configuration after Grace Period,
Required?	0..*, Required if Package Configuration is entered
Data Type & Length	Alphanumeric, 6-23 depending on Issuing Agency

Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public
GS1 GDSN	
Attribute Name	ChildTradeItem\globalTradeItemNumber

Definition

A particular Global trade item Number, a numerical value used to uniquely identify a trade item. A trade item is any trade item (trade item or service) upon which there is a need to retrieve pre-defined information and that may be planned, priced, ordered, delivered and or invoiced at any point in any supply chain.

Data Type	Identifier (14 digits)
GDSN Required	DEPENDENT

Population Guidance (below)

The GUDID Package attributes are populated as a group and can not be entered as single elements in the message. These attributes are:

- Package DI Number
- Quantity per Package
- Contains DI Package
- Package Type
- Package Discontinue Date

All packages must be entered. If a new package level is created, it is to be added to the GUDID as part of the Primary DI to which it is applicable.

This GDSN attribute references the quantity of the child trade item (GUDID- Contains DI Package) which is contained in the GTIN (GUDID- Package DI Number). See the example below.

This GDSN attribute references the hierarchy level which is the next level below, or Child of, the globalTradeitemNumber (GUDID- Package DI Number). See the example below.

In GDSN, the following is provided.

Hierarchy Number 1

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
2061414111111c	CASE	1061414111111c	5	5 cartons in a case
1061414111111c	PACK_OR_INNER_PACK	0061414111111c	4	4 boxes in a carton
0061414111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

Hierarchy Number 2

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
4061414111111c	CASE	3061414111111c	2	2 cartons in a case
3061414111111c	PACK_OR_INNER_PACK	0061414111111c	10	10 boxes in a carton

globalTradeitemNumber	tradeItemUnitDescriptor	ChildTradeItem/globalTradeItemNumber	quantityofNextLowerLevelTradeItem	Notes
00614141111111c	BASE_UNIT_OR_EACH	N/A	N/A	1 Box of Gloves

- This is converted to the following for population in the GUDID.

Package DI Number	Quantity per package	Contains DI Package	Notes
10614141111111c	4	00614141111111c	Indicates there are 4 eaches in the pack
20614141111111c	5	30614141111111c	Indicates there are 5 packs in the case
30614141111111c	10	00614141111111c	Indicates there are 10 eaches in the pack
40614141111111c	2	30614141111111c	Indicates there are 2 packs in the case

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be deleted.

22. Package Type

FDA GUDID

Description - Text to describe the outer packaging of the product and enables users to understand higher level packaging configurations.

Data Entry Notes	Free text.
Edit Rules After Grace Period but cannot delete	Can add with new package configuration after Grace Period,
Required?	0..1 Not Required
Data Type & Length	Alphanumeric, 20
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Private

GS1 GDSN

Attribute Name packagingTypeCode

Definition - The code identifying the type of package used as a container of the trade item.

Data Type	Text (1-3 characters)
GDSN Required	Optional

Population Guidance (below)

The GDSN attribute is a code list and is mapped to the values needed for the GUDID. In GDSN the packaging type code is a 3 character code to identify the type of packaging used for the globalTradeItemNumber. In this case, this value refers to the globalTradeItemNumber which is

being used to populate the GUDID Package DI Number. The GUDID is asking for a descriptive term and not the code. There is a mapping list from which the data pools can populate the appropriate descriptive term to publish to the GUDID.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be deleted.

23. Package Discontinue Date

FDA GUDID

Description - Indicates the date this particular package configuration is discontinued by the Labeler.

Data Entry Notes - Choose date from calendar or manually enter in format (mm/dd/yyyy).

Edit Rules After Grace Period - Can add with new package configuration after Grace Period, but cannot delete.

Required? - 0..* Required if both Package Configuration and Commercial Distribution End Date are entered

Data Type & Length	Numeric date format, 10
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	discontinuedDate

Definition Communicate the date on which the trade item is no longer to be manufactured. Allows the reuse of the GTIN after 48 months with the explicit exception of Apparel, being 30 months and the implicit exception for specialty products (e.g., steel beams).

Data Type	Date Time (CCYY-MM-DDTHH:MM:SS)
GDSN Required	Optional

Population Guidance (below)

This attribute is populated from the globalTradeItemNumber which is being used to populate the GUDID Package DI Number. This date is the date when the Package DI has been discontinued or removed from the marketplace.

If the Primary DI has reached its lastShipDate, then any Package DI attached to the Primary DI will need to have a discontinueDate populated. This ensures that a Package is not active and its contents are not.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute cannot be deleted.

24. Package Status

FDA GUDID

Description - Indicates whether the package configuration is available or discontinued.

Data Entry Notes	System populated.

Edit Rules After Grace Period	N/A
Required?	0..* Required if Published
Data Type & Length	Alphanumeric
Entry List of Values (LOV)	In Commercial Distribution; Not in Commercial Distribution
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Derived by the FDA GUDID based on effectiveDate and lastShipDate

Definition	N/A
Data Type	N/A
GDSN Required	N/A

Population Guidance (below)

If the current date is equal to or greater than the GUDID Publication Date (effectiveDate in GDSN) of the Primary DI, then the Package Status will be set to “In Commercial Distribution” automatically by the FDA. If the current date is equal to or greater than the GUDID Package Discontinue Date (lastShipDate for the package level GTIN in GDSN), then the Package Status will be set to “Not in Commercial Distribution” automatically by the FDA. Note, if the Commercial Distribution Status of the Primary DI is set to “Not in Commercial Distribution”, the Package Status will also be set to “Not in Commercial Distribution”.

25. Support Contact Phone

FDA GUDID

Description	Phone number for the support contact.

Data Entry Notes - Enter 10 digit North American number. For international numbers, start with "+" Does not require the use of () or -, but can enter these symbols.

Edit Rules After Grace Period	Can edit, add, or delete after Grace Period.
Required?	1..* Required if support contact information is entered
Data Type & Length	Numeric, 20 (10)
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name — Pair of attributes in combination

a. contactType
b. communicationChannelCode
c. communicationNumber

Definition

a. The general category of the contact party for a trade item for example Purchasing.

b. Means used to communicate with another party.

c. Number assigned to a specific means of communication.

Data Type

a. Code List

b. Code List (Multiple Occurrence)

c. Text (1-70 characters) (Multiple Occurrence)

GDSN Required- OPTIONAL, however if any of the three is provided, an instance of all three are required

Population Guidance (below)

The GDSN attribute contactType signifies which type of contact information is being provided. For end user or consumer support, the code value should be “CONSUMER_SUPPORT”. For the item’s regulatory contact information, the code value should be “LICENSEE_REGISTRAR”. The GDSN attributes communicationChannelCode and communicationNumber can repeat as a pair of attributes for a single contactType. There can be more than one contactType populated for a single Trade item.

For the GUDID, the contactType of “CONSUMER_SUPPORT” will signify the information to be provided to the GUDID via GDSN. Where an instance of the GDSN attribute communicationChannelCode is populated with the value of “TELEPHONE”, the corresponding communicationNumber will map to the GUDID attribute Support Contact Phone.

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Support Contact Phone and Support Contact Email.

26. Support Contact Email

FDA GUDID

Description	Email for the support contact
Data Entry Notes	Enter alphanumeric email address in format ---@--.--
Edit Rules After Grace Period	Can edit, add, or delete after Grace Period.
Required?	1..* Required if support contact information is entered
Data Type & Length	Alphanumeric, 100
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name- Pair of attributes in combination

a. contactType

b. communicationChannelCode

c. communicationNumber

Definition

a. The general category of the contact party for a trade item for example Purchasing.

b. Means used to communicate with another party.

c. Number assigned to a specific means of communication.

Data Type

a. Code List

b. Code List (Multiple Occurrence)

c. Text (1-70 characters) (Multiple Occurrence)

GDSN Required- OPTIONAL, however if any of the three is provided, an instance of all three are required

Population Guidance (belwo)

The GDSN attribute contactType signifies which type of contact information is being provided. For end user or consumer support, the code value should be “CONSUMER_SUPPORT”. For the item’s regulatory contact information, the code value should be “LICENSEE_REGISTRAR”. The GDSN attributes communicationChannelCode and communicationNumber can repeat as a pair of attributes for a single contactType. There can be more than one contactType populated for a single Trade item.

For the GUDID, the contactType of “CONSUMER_SUPPORT” will signify the information to be provided to the GUDID via GDSN. Where an instance of the GDSN attribute communicationChannelCode is populated with the value of “EMAIL”, the corresponding communicationNumber will map to the GUDID attribute Support Contact Email.

Where an instance of the GDSN attribute communicationChannelCode is populated with the value of “EMAIL”, the corresponding communicationNumber will map to this GUDID attribute.

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Support Contact Phone and Support Contact Email.

27. Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)

FDA GUDID

Description – Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3.

Data Entry Notes	Check box if appropriate. (Webtool)
Edit Rules After Grace Period	Can add or delete after Grace Period.
Required?	0..1 Not Required
Data Type & Length	Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name doesTradeItemContainHumanTissue

Definition The trade item has, as a component or ingredient, human tissue. The amount of tissue is not limited to a certain amount, any amount will cause a flag of “TRUE”.

Data Type Boolean

GDSN Required	OPTIONAL

Population Guidance (below)

This Boolean attribute should be populated with a value of “TRUE” when there is any amount of human tissue as part of the device. Otherwise the value should default to FALSE.

28. Kit

FDA GUDID

Description – Indicates that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and is being distributed as a medical device.

Data Entry Notes - Check box if DI record is for the kit itself. Do not check if the product is part of a kit. (Webtool)

Edit Rules After Grace Period	Cannot add or delete after Grace Period.
Required?	0..1 Not Required
Data Type & Length	Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Temporary population until final GDSN deployment

groupedProduct (value populated in GDSN is KIT)

Definition- Code representing if the trade item is considered by the manufacturer to be more than a single item, such as a kit, combination item.

Data Type	Text
GDSN Required	Optional
Final Deployment Attribute Name	groupedProduct (value populated in GDSN is KIT)
Definition	Code representing if the trade item is considered by the manufacturer to be more than a single item, such as a kit, combination item.
Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- groupedProduct. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

The GDSN attribute groupedProduct is a code list attribute. It is used to specify if an item is a kit or a combination product. A value populated for the GDSN attribute groupedProduct of “KIT” will populate a value of “TRUE” for the GUDID attribute Kit. Any other value, or when no value is provided, for the GDSN attribute will populate a value of “FALSE” for the GUDID attribute Kit.

This attribute will be used to provide several sets of information and as such may be repeated. GUDID attributes using this group of attributes are Kit and Combination Product.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

29. Combination Product

FDA GUDID

Description – Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case.

Data Entry Notes - Check box if DI record is for the combination product itself. Do not check if the product is a constituent part of a combination product. (Webtool)

Edit Rules After Grace Period	Cannot add or delete after Grace Period.
Required?	0..1 Not Required
Data Type & Length	Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Temporary population until final GDSN deployment

groupedProduct (value populated in GDSN is COMBINATION)

Definition- Code representing if the trade item is considered by the manufacturer to be more than a single item, such as a kit, combination item.

Data Type	Text
GDSN Required	Optional

Final Deployment Attribute Name

groupedProduct (value populated in GDSN is COMBINATION)

Definition Code representing if the trade item is considered by the manufacturer to be more than a single item, such as a kit, combination item.

Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (belwo)

This attribute has a temporary attribute (AVP) in GDSN- groupedProduct. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

The GDSN attribute groupedProduct is a code list attribute. It is used to specify if an item is a kit or a combination product. A value populated for the GDSN attribute groupedProduct of “COMBINATION” will populate a value of “TRUE” for the GUDID attribute Combination Product. Any other value, or when no value is provided, for the GDSN attribute will populate a value of “FALSE” for the GUDID attribute Combination.

This attribute will be used to provide several sets of information and as such may be repeated. GUDID attributes using this group of attributes are Kit and Combination Product.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

30. Device Exempt from Premarket Authorization

FDA GUDID

Description	Device is exempt from FDA Premarket regulations; or a pre-amendment device.
Data Entry Notes	Check box if appropriate.
Edit Rules After Grace Period	Cannot add or delete after Grace Period.
Required?	0..1 Not Required, Required if device is exempt from premarket submission
Data Type & Length	Boolean
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Temporary population until final GDSN deployment-

exemptFromFDAPreMarketAuthorization

Definition- Device is exempt from FDA Premarket regulations. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing clearance. Please note that some Class III pre-amendment devices may require a Class III 510(k). See "Historical Background2" for additional information.

Data Type	Text
GDSN Required	Optional

Final Deployment Attribute Name-

exemptFromFDAPreMarketAuthorization

Definition- Device is exempt from FDA Premarket regulations. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices. Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing clearance.

Please note that some Class III pre-amendment devices may require a Class III 510(k). See "Historical Background2" for additional information.

Data Type	BOOLEAN
GDSN Required	OPTIONAL

Population Guidance (belwo)

This attribute has a temporary attribute (AVP) in GDSN- exemptFromFDAPreMarketAuthorization. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

This Boolean attribute is used to denote if an item is such that is does not require a pre-market authorization from the FDA (termed an exemption. A value of “TRUE” for this GDSN attribute signifies that the item has been deemed exempt from needing this type of review. A value of “FALSE” or a “NULL” value will signify that an authorization is required for the item.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

31. FDA Premarket Submission Number

FDA GUDID

Description – Number associated with the regulatory decision regarding the applicant’s legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA.

Data Entry Notes	Enter all valid FDA Premarket Submission Numbers.
Edit Rules After Grace Period	Can add after Grace Period, but cannot delete or edit.
Required?	1..* Required, Not required if Device Exempt from Premarket Submission is selected, Not required for Kits, Required for HCT/Ps
Data Type & Length	Alphanumeric, 8
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Temporary population until final GDSN deployment

fDA510KPremarketAuthorization

Definition- Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. These values are the 510K Premarket Authorization Numbers assigned to the item.

Data Type	Text
GDSN Required	Optional
Final Deployment Attribute Name	Pair of attributes in combination

a. additionalClassificationAgencyName (Code for “FDA_510K_PREMARKET_NOTIFICATION”)

b. additionalClassificationCategoryCode

Definition

a. Text name of the additional external classification agency whose schema is being provided in addition to the Global EAN.UCC schema. Required if additional classification schema fields are populated.

b. Category code based on alternate classification schema chosen in addition to EAN/UCC classification schema.

Data Type

a. Code List (Multiple Occurrence)

b. Text (1-35 characters) (Multiple Occurrence)

GDSN Required- OPTIONAL, however if one of the pair is populated the other must be populated.

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- fDA510KPremarketAuthorization. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

This set of attributes will allow for the population of a Pre-Market Authorization number for the device. This number will correlate to the scientific and regulatory review information which was created to evaluate the safety and efficacy of the device. This set of attributes is required to be provided when the value populated for the GDSN attribute exemptFromFDAPreMarketAuthorization is not “TRUE”.

This set of attributes will also be used to populate several other pieces of information- FDA Product Code, FDA Premarket Submission Number, and GMDN. For supply chain use, this set of attributes can also provide the UNSPSC codes for the device.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but can not be edited or deleted.

32. Supplement

FDA GUDID

Description Number assigned by FDA to a supplemental application for approval of a change in a medical device with an approved PMA, HDE, or PDP.

Data Entry Notes Enter all valid Supplement Numbers. Do not enter any alpha characters.

Edit Rules After Grace Period Can add after Grace Period, but cannot delete or edit.

Required? 0..1 Not Required unless Device contains Supplement. Not required if Device Exempt from Premarket Submission is selected. Not required for Kits.

Data Type & Length Numeric, 4

Entry List of Values (LOV) N/A

New DI Trigger? NO

Public/Private Status Public

GS1 GDSN

Temporary population until final GDSN deployment-

fDASupplementNumber

Definition- Number associated with the regulatory decision regarding the applicant's legal right to market a medical device (PMA Supplement). After FDA has approved a PMA, an applicant must submit a PMA supplement for review and approval by FDA before making any change affecting the safety or effectiveness of the device unless FDA has advised that an alternate type of submission is permitted for a particular change. All changes must meet the requirements of the Quality System regulation (Good Manufacturing Practices) under 21 CFR Part 820 including the design control requirement under §820.30. Changes for which an applicant must submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device: new indication for use of the device; labeling changes; the use of a different facility or establishment to manufacture, process, sterilize, or package the device; changes in manufacturing facilities, methods, or quality control procedures; changes in sterilization procedures; changes in packaging; changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device; and extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by FDA. [If the protocol has been previously approved by FDA, a supplement is not submitted but the change must be reported to FDA in the post approval periodic reports as described in the §814.39(b).]

Data Type	Text
GDSN Required	Optional
Final Deployment Attribute Name	fDASupplementNumber

Definition- Number associated with the regulatory decision regarding the applicant's legal right to market a medical device (PMA Supplement). After FDA has approved a PMA, an applicant must submit a PMA supplement for review and approval by FDA before making any change affecting the safety or effectiveness of the device unless FDA has advised that an alternate type of submission is permitted for a particular change. All changes must meet the requirements of the Quality System regulation (Good Manufacturing Practices) under 21 CFR Part 820 including the design control requirement under §820.30. Changes for which an applicant must submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device: new indication for use of the device; labeling changes; the use of a different facility or establishment to manufacture, process, sterilize, or package the device; changes in manufacturing facilities, methods, or quality control procedures; changes in sterilization procedures; changes in packaging; changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device; and extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by FDA. [If the protocol has been previously approved by FDA, a supplement is not submitted but the change must be reported to FDA in the post approval periodic reports as described in the §814.39(b).]

Data Type	Integer
GDSN Required	OPTIONAL

Population Guidance

This attribute has a temporary attribute (AVP) in GDSN- fDASupplementNumber. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

This is the FDA identification number associated to the regulatory decision regarding the applicant's legal right to market a medical device (PMA Supplement).

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but can not be edited or deleted.

33. Product Code

FDA GUDID

Description - Classification for pre-market devices issued by the FDA; three letter code.

Data Entry Notes	Enter all applicable Product Codes.
Edit Rules After Grace Period	Can edit, add, or delete after Grace Period.

Required - 0..* Required for all medical devices except for Kits or IVDs (BL premarket submission number)

Data Type & Length	Alpha, 3
Entry List of Values (LOV)	FDA Product Code list
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name — Pair of attributes in combination

a. additionalClassificationAgencyName

b. additionalClassificationCategoryCode

Definition

a. Text name of the additional external classification agency whose schema is being provided in addition to the Global EAN.UCC schema. Required if additional classification schema fields are populated.

b. Category code based on alternate classification schema chosen in addition to EAN/UCC classification schema.

Data Type

a. Code List (Multiple Occurrence)

b. Text (1-35 characters) (Multiple Occurrence)

GDSN Required - OPTIONAL, however if one of the pair is populated the other must be populated.

Population Guidance (below)

This repeatable set of attributes will allow for the population of a FDA Product Code for the device. This can be accomplished by the population of the code value “43” in the GDSN attribute additionalClassificationAgencyName. The actual Product Code can then be populated using the associated value in the GDSN attribute additionalClassificationCategoryCode.

This set of attributes will also be used to populate several other pieces of information- FDA Product Code, FDA Premarket Submission Number, and GMDN. For supply chain use, this set of attributes can also provide the UNSPSC codes for the device.

34. Product Code Name

FDA GUDID

Description	Name associated with the three-letter Product Code.
Data Entry Notes	System populated
Edit Rules After Grace Period	N/A

Required?	1..1, Required with Product Code
Data Type & Length	Alphanumeric, 360
Entry List of Values (LOV)	FDA Product Code list
New DI Trigger?	NO
Public/Private Status	Public
GS1 GDSN	
Attribute Name	N/A
Definition	N/A
Data Type	N/A
GDSN Required	N/A

Population Guidance (below)

The FDA will automatically populate the GUDID with a value for this attribute based on the Product Code submitted.

35. FDA Listing Number

FDA GUDID

Description – Number assigned by FDA during Registration and Listing to all devices in commercial distribution, regardless of pre-market authorization requirements per 21 CFR 807.28(f).

Data Entry Notes	Enter all applicable Listing Numbers
Edit Rules After Grace Period	Can add after Grace Period, but cannot delete or edit.

Required? - 0..* Required for all medical devices except for HCT/Ps, Kits, and IVDs (BL premarket submission number).

Data Type & Length	Alphanumeric, 7
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Private

GS1 GDSN

Temporary population until final GDSN deployment-

fDAMedicalDeviceListing

Definition- Most Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to list the devices that are made at their facility and the activities that are performed on those devices. Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

Data Type	Text
GDSN Required	Optional
Final Deployment Attribute Name	Pair of attributes in combination

a. additionalTradeItemIdentificaton\type(Code of “FDA_MEDICAL_DEVICE_LISTING”)

b. additionalTradeItemIdentificaton\value

Definition

a. Type of the identification system that is being used as an alternative to the Global Trade Item Number.

b. Alternative means to the Global Trade Item Number to identify a trade item.

Data Type

a. Code List (Multiple Occurrence)

b. Text (Multiple Occurrence)

GDSN Required- OPTIONAL, however if one of the pair is populated the other must be populated.

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- fDAMedicalDeviceListingNumber. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

The GUDID is asking for the FPD Medical Device Listing number assigned to the device. This repeatable set of attributes will allow for the population of a FDA Medical Device Listing Number for the device. This can be accomplished by the population of the code value “FDA_MEDICAL_DEVICE_LISTING” in the GDSN attribute additionalPartyIdentification/type. The actual FDA Medical Device Listing # can then populated in the GUDID using the associated additionalPartyIdentification\value(s).

This group attributes will be used to provide several sets of information and as such will be repeated as a group. GUDID attributes using this group of attributes are Version or Model Number, Catalog Number, Secondary DI Number, and FDA Listing Number.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but can not be edited or deleted.

36. Code

FDA GUDID

Description - Unique numerical five-digit code used to generically identify medical devices and related health care products.

Data Entry Notes	Enter all applicable GMDN Preferred Term Codes.
Edit Rules After Grace Period	Can edit, add, or delete after Grace Period.
Required?	..* Required
Data Type & Length	Numeric, 5
Entry List of Values (LOV)	GMDN list
New DI Trigger?	NO
Public/Private Status	Private

GS1 GDSN

Attribute Name — Pair of attributes in combination

a. additionalClassificationAgencyName

b. additionalClassificationCategoryCode

Definition

a. Text name of the additional external classification agency whose schema is being provided in addition to the Global EAN.UCC schema. Required if additional classification schema fields are populated.

b. Category code based on alternate classification schema chosen in addition to EAN/UCC classification schema.

Data Type

a. Code List (Multiple Occurrence)

b. Text (1-35 characters) (Multiple Occurrence)

GDSN Required - OPTIONAL, however if one of the pair is populated the other must be populated.

Population Guidance (below)

This repeatable set of attributes will allow for the population of a FDA Product Code for the device. This can be accomplished by the population of the code value “35” in the GDSN attribute additionalClassificationAgencyName. The actual GMDN Code can then be populated using the associated value in the GDSN attribute additionalClassificationCategoryCode. Only the GMDN Code will be populated in the GUDID.

This set of attributes will also be used to populate several other pieces of information- FDA Product Code, FDA Premarket Submission Number, and GMDN. For supply chain use, this set of attributes can also provide the UNSPSC codes for the device.

The population of a GMDN Code via GDSN has been available for some time. While the FDA will not make the code available to the Public in the GUDID, GDSN will pass the code along to normal GDSN recipients for their use following their existing processes.

37. Name

FDA GUDID

Description	Name associated with the GMDN Preferred Term Code.
Data Entry Notes	System populated based on GMDN Preferred Term Code.
Edit Rules After Grace Period	N/A
Required?	1..1, Required
Data Type & Length	Alphanumeric
Entry List of Values (LOV)	GMDN
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	additionalClassificationCategoryDescription
Definition	In the additional classification system, the description of the category.
Data Type	Text (1-70 characters)
GDSN Required	Optional
Population Guidance (below)	

The FDA will automatically populate the GUDID with a value for this attribute based on the Code (GMDN) submitted. Publishing the description field with the classification code name or description will provide additional value to supply chain partners receiving the message.

The population of a GMDN Code via GDSN has been available for some time. While the FDA will not make the code available to the Public in the GUDID, GDSN will pass the code along to normal GDSN recipients for their use following their existing processes.

38. Definition

FDA GUDID

Description	Description associated with the GMDN Preferred Term Code.
Data Entry Notes	System populated based on GMDN Preferred Term Code.
Edit Rules After Grace Period	N/A
Required?	1..1, Required
Data Type & Length	Alphanumeric
Entry List of Values (LOV)	GMDN list
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	N/A
Definition	N/A
Data Type	N/A
GDSN Required	1..1, Required

Population Guidance (below)

The FDA will automatically populate the GUDID with a value for this attribute based on the Code (GMDN) submitted.

39. For Single Use

FDA GUDID

Description – Indicates that the device is intended for one use or on a single patient during a single procedure.

Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Cannot edit after Grace Period.
Required?	1..1, Required
Data Type & Length	N/A
Entry List of Values (LOV)	Yes/No
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Attribute Name	manufacturerDeclaredReusabilityType

Definition- Determines if the product is intended for single or multiple uses; including the number of validated cycles and the number of times a product can be used according to the manufacturer specifications. It is suggested that medical providers consult the device manufacturer's Instruction For Use (IFU) for full reusability instructions.

Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This attribute is a code list stating if the item can be used again. When a value of "SINGLE_USE" or "REUSABLE_SAME_PATIENT" are populated for the GDSN attribute manufacturerDeclaredReusabilityType, the GUDID will be populated with a value of "TRUE" signifying the device is intended for one use or on a single. For all other values populated in the GDSN attribute manufacturerDeclaredReusabilityType, the GUDID will be populated with a value of "FALSE" signifying the device can be used more than one time.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

40. Lot or Batch Number

FDA GUDID

Description – Flag to indicate the device is managed by lot or batch number. This number can be found on the device label or packaging. Lot or Batch means one finished device or more that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Can edit after Grace Period.
Required?	1..1, Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	hasBatchNumber

Definition- Indication whether the base trade item is batch or lot number requested by law, not batch or lot number requested by law but batch or lot number allocated, or not batch or lot number allocated. A batch or lot number is a manufacturer assigned code used to identify a trade items trade item on batch or lot. Differs from Serial Number, which is a manufacturer assigned code during the trade item on cycle to identify a unique trade item.

Data Type	Boolean
GDSN Required	OPTIONAL

Population Guidance (below)

This attribute is a Boolean clarifying how the item is controlled. It is not for the population of actual lot or batch numbers. Neither the GUDID nor GDSN are used to provide actual Batch or Lot numbers. These should be communicated in transactional documents such as packaging, shipping and invoice documents.

A value populated of "TRUE" signifies that the device has, as one of its controls, a batch or lot number. It also signifies that the batch or lot number will be printed on the packaging and in the UDI.

41. Manufacture Date

FDA GUDID

Description - Flag to indicate the device is managed by date of manufacture; the date a specific device was manufactured.

Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Can edit after Grace Period.
Required?	1..1, Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Temporary population until final GDSN deployment-

isTradeItemManagedByManufactureDate

Definition- Indication whether the trade item is managed by manufacture date. A positive response indicates the manufacturer utilizes the manufacture date to control the item instead of lot and batch numbers.

Data Type	Boolean
GDSN Required	Optional

Final Deployment Attribute Name

tradeItemDateOnPackagingTypeCode (coming in Major Release in 2016)

Definition - Indicates the type of date marked on the packaging for example Best Before Date.

Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN

isTradeItemManagedByManufactureDate.

It will be deployed into the GDSN Schema in 2016 into a final solution.

This GUDID attribute is a Boolean clarifying how the item is controlled. It is not for the population of actual manufacturing dates. Neither the GUDID nor GDSN are used to provide actual manufacturing dates. These should be communicated in transactional documents such as packaging, shipping and invoice documents.

A value populated of “TRUE” for the temporary attribute or of “PRODUCTION_DATE” for the attribute tradeItemDateOnPackagingTypeCode signifies that the item has, as one of its controls, a manufacture date. It also signifies that the manufacture date will be printed on the packaging and in the UDI.

42. Serial Number

FDA GUDID

Description – Flag to indicate the device is managed by serial number. This number can be found on the device label or accompanying packaging; it is assigned by the labeler and should be specific to each device.

Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Can edit after Grace Period.
Required?	1..1, Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name serialNumberLocationCode

Definition - The location on the item or packaging of a serial number. A serial number is a code, numeric or alphanumeric, assigned to an individual instance of an entity for its lifetime for example a Microscope model AC-2 with serial number 1234568 and microscope model AC-2 with serial number 1234569.

Data Type	Text (1-35 characters) (External Code List)
GDSN Required	OPTIONAL

Population Guidance (below)

This GUDID attribute is a Boolean clarifying how the item is controlled. It is not for the population of an actual serial number(s). Neither the GUDID nor GDSN are used to provide an actual serial numbers(s). These should be communicated in transactional documents such as packaging, shipping and invoice documents.

A GUDID value of “TRUE” signifies that the item has, as one of its controls, a serial number(s). It also signifies that the manufacture date will be printed on the packaging and in the UDI.

This GDSN attribute is a code list attribute designating where the serial number can be found on the item or its packaging, if present. If a value is populated for the GDSN attribute of “MARKED_ON_PACKAGING”, “MARKED_ON_PACKAGING_INSERT”, or “MARKED_ON_TRADE_ITEM”, it signifies that the item has, as one of its controls, a serial number and a value of “TRUE” will populated for the GUDID attribute. It also signifies that the serial number will be printed on the packaging and in the UDI. Any other code value published in GDSN will populate a value of “FALSE” for the GUDID attribute.

43. By Expiration Date

FDA GUDID

Description - Flag to indicate the device is managed by expiration date. The date by which the label of a device states that the device must or should be used.

Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Can edit after Grace Period.
Required?	1..1, Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Current GDSN Attribute packagingMarkedExpirationDateType

Definition - Indicates the type of expiration date marked on the packaging for example Best Before Date.

Data Type	Code List
GDSN Required	OPTIONAL

Final Deployment Attribute Name-

tradeItemDateOnPackagingTypeCode (coming in Major Release in 2016)

Definition - Indicates the type of date marked on the packaging for example Best Before Date.

Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This attribute has a current attribute in GDSN- packagingMarkedExpirationDateType. It will be changed in the GDSN Major Release in 2016 into the attribute tradeItemDateOnPackagingTypeCode.

This GUDID attribute is a Boolean clarifying how the item is controlled. It is not for the population of actual expiration dates. Neither the GUDID nor GDSN are used to provide actual expiration dates. These should be communicated in transactional documents such as packaging, shipping and invoice documents.

A value populated of “BEST_BEFORE_DATE” or “EXPIRY_DATE” for the current GDSN attribute packagingMarkedExpirationDateType or of “BEST_BEFORE_DATE” or “EXPIRATION_DATE” for the attribute tradeItemDateOnPackagingTypeCode signifies that the item has, as one of its controls, an expiration date. It also signifies that the expiration date will be printed on the packaging and in the UDI.

44. Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)

FDA GUDID

Description – Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. Choosing yes indicates that the device label or packaging contains one of the following statements: (1) "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions", (2) This Product Contains Dry Natural Rubber", (3) Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" or (4) "The Packaging of This Product Contains Dry Natural Rubber".

Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Cannot edit after Grace Period.
Required?	1..1, Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Attribute Name	doesTradeItemContainLatex

Definition - An indication that a trade item is made from or contains latex which refers generically to a stable dispersion (emulsion) of polymer microparticles in an aqueous medium.

Data Type	Non-Binary Logic
GDSN Required	OPTIONAL

Population Guidance (below)

This GDSN attribute is a Non-Binary Logic Code List with the values of “TRUE”, “FALSE”, “NOT_APPLICABLE”, and “UNSPECIFIED”. For the US Target Market, the only values, which can be used are “TRUE” and “FALSE” for medical devices. All other values should not be accepted for a GDSN Target Market value of 840 (US).

Application of the value is based upon whether a mark exists on the packaging as to latex being contained in the device or its packaging. If a mark is required to be on the package, this attribute is populated with “TRUE”. If no mark is required, then this attribute is populated with “FALSE”. This is based on the regulation, which basically states that if there is latex present a label mark must be placed on the packaging.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

45. Device labeled as "Not made with natural rubber latex”

FDA GUDID

Description - Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container. Only applicable to devices not subject to the requirements under 21 CFR 801.437.

Data Entry Notes Check box if appropriate. (Webtool) Only applicable if the response to "Device required to be labeled as containing natural rubber latex or dry natural rubber" was "No".

Edit Rules After Grace Period – If selected "Yes" to "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)", cannot add or delete check to this field. If selected "NO" to "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)", can add or delete check to this field.

Required?	0..1 Not Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	packageMarksFreeFrom

Definition Indication of the food ingredients that the package is marked free from.

Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This GDSN attribute is a code list of values representing markings on the packaging. The markings signify the device is “Free-from” certain ingredients (irritants or allergens). This GDSN attribute is only populated to signify what is called out in one of these markings. The device might be free from one or more of the ingredients signified by a code value in the code list. However, the actual code value is only populated here if there is an actual mark on the package calling out the ingredient is not present.

If a value of “FREE_FROM_LATEX” is published in the GDSN attribute packageMarksFreeFrom attribute, a value of “TRUE” will be populated in the GUDID. Any other code value published in GDSN will populate a value of “FALSE” for this GUDID attribute.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be edited, but only under certain circumstances. See Edit Rules After Grace Period for more details

46. Prescription Use (Rx)

FDA GUDID

Description	Indicates that the device requires a prescription to use.
Data Entry Notes	Select check box if appropriate (Webtool)
Edit Rules After Grace Period	Can add or delete after Grace Period.
Required?	0..1 Not Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	ConsumerSalesCondition
Definition	A code depicting restrictions imposed on the Trade Item regarding how it can be sold to the consumer for example Prescription Required.
Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This GDSN attribute is a code list of values signifying how the item is presented for sale to a consumer.

If a value of "PRESCRIPTION_REQUIRED" is published in the GDSN attribute ConsumerSalesCondition attribute, a value of "TRUE" will be populate in the GUDID. Any other code value published in GDSN will populate a value of "FALSE" for this GUDID attribute.

47. Over the Counter (OTC)

FDA GUDID

Description - Indicates that the device does not require a prescription to use and can be purchased over the counter (OTC).

Data Entry Notes	Select check box if appropriate (Webtool)
Edit Rules After Grace Period	Can add or delete after Grace Period.
Required?	0..1 Not Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	ConsumerSalesCondition

Definition - A code depicting restrictions imposed on the Trade Item regarding how it can be sold to the consumer for example Prescription Required.

Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This GDSN attribute is a code list of values signifying how the item is presented for sale to a consumer.

If a value of "OTC" is published in the GDSN attribute ConsumerSalesCondition attribute, a value of "TRUE" will be populate in the GUDID. Any other code value published in GDSN will populate a value of "FALSE" for this GUDID attribute.

48. Is the device labeled for MRI Safety?

FDA GUDID

Description - Indicates that sufficient testing has been conducted to characterize the behavior of the device in the MR environment. See ASTM F2503-13.

Data Entry Notes	Check box if appropriate. (Webtool)
Edit Rules After Grace Period	Can add check to checkbox after Grace Period, but cannot delete a check from the checkbox.
Required?	0..1 Not Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	N/A- LOGICAL POPUALTION
Definition	N/A
Data Type	N/A
GDSN Required	N/A

Population Guidance (below)

LOGICAL POPULATION- On the outbound GUDID Message by the Data Pool. Will use the value "TRUE" when any code value other than “UNSPECIFIED” or “MRI_UNSAFE” is published in the GDSN attribute mRICompatibility. By using GDSN, the GTIN of the lowest level of the hierarchy will become the Primary DI.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can only be changed to a value of “TRUE” from a value of “FALSE”. If the value needs to be changed to a value of “FALSE” from a value of “TRUE”, a new UDI will be required.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but can not be deleted.

49. MRI Safety Status

FDA GUDID

Description – Indicates the MR safety status of the device. The three drop down values are: MR Safe, MR Conditional, and MR Unsafe. Please see the ASTM F2503-13 standard for more information on these three values.

Data Entry Notes Must select one value from drop-down if selected check box for "Has the device been evaluated for MRI Safety?" (Webtool)

Edit Rules After Grace Period – Can add MRI Safety Status after Grace Period only if the field 'Has the device been evaluated for MRI Safety?' was previously unchecked. Cannot edit after Grace Period if 'Has the device been evaluated for MRI Safety?' was previously checked.

Required? 1..* Required if selected check box for "Is the device labeled for MRI Safety?"

Data Type & Length	N/A
Entry List of Values (LOV)	MR Safe, MR Unsafe, MR Conditional
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	mRICompatibility

Definition This is an identification of the compatibility of a trade item for use in the presence of a Magnetic Resonance Imaging (MRI) system.

Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This GDSN attribute is a code list of values signifying if the device is safe for use in an MRI environment.

All GDSN code values map to an applicable GUDID code value. While it is not recommended to use a GDSN value of UNSPECIFIED as this provides no useful information and can lead to confusion in a clinical setting. However, if a GDSN value of UNSPECIFIED is published, this will be mapped to MR Unsafe as a default

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be edited, but only under certain circumstances. See Edit Rules After Grace Period for more details

50. Size Type

FDA GUDID

Description	Dimension type for the clinically relevant measurement of the medical device.
Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Can add after Grace Period, but cannot delete or edit.
Required?	0..* Not Required, Required if Size is provided
Data Type & Length	N/A

Entry List of Values (LOV) – Circumference; Depth; Device Size Text, specify; French Catheter Gauge; Greatest Diameter; Height; Length; Lumen Diameter; Needle Gauge; Second Greatest Diameter; Third Greatest Diameter; Total Volume; Width

New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Temporary population until final GDSN deployment

clinicalSizeType

Definition The qualifier to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user. For example "needle gauge" for a 16 gauge needle, or "volume" for a 200 cc syringe.

Data Type	Code List
GDSN Required	OPTIONAL
Final Deployment Attribute Name	clinicalSizeType

Definition The qualifier to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user. For example "needle gauge" for a 16 gauge needle, or "volume" for a 200 cc syringe.

Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- clinicalSizeText. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

All of the clinical attributes can be repeated as a group when this value changes.

This GUDID attribute is a Code List clarifying the qualifier (type) associated to the clinical size values. For example as syringe is measured by the gauge of the needle and/or the volume it can contain. For the type, this attribute might be populated with “NEEDLE_GAUGE” and/or “TOTAL_VOLUME”. This attribute is part of a repeatable class of clinical attributes for the device containing the Size Type, Size Value and Size Unit of Measure for the device’s clinical size.

There is an option to specify a textual value for a clinical size type, which has not been specified in the value and UoM attributes.

When this attribute is published with the value of “DEVICE_SIZE_TEXT,_SPECIFY”, the GDSN attribute clinicalSizeText becomes required.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but can not be edited or deleted.

51. Size Value

FDA GUDID

Description	Numeric value for the clinically relevant size measurement of the medical device.
Data Entry Notes	Enter numeric value.
Edit Rules After Grace Period	Can add after Grace Period, but cannot delete or edit.
Required?	1..* Required if Size is provided
Data Type & Length	Numeric (1-40 digits)
Entry List of Values (LOV)	
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Temporary population until final GDSN deployment-

clinicalSizeValue

Definition - The value to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user. For example 16 gauge for a needle, or 200 cc for a syringe. Carries a UoM from the Recommendation 20 code list.

Data TypeNumeric

GDSN Required OPTIONAL

Final Deployment Attribute Name clinicalSizeValue

Definition- The value to denote the dimensional size, which is clinically relevant for the use of the trade item by the clinical user. For example 16 gauge for a needle, or 200 cc for a syringe. Carries a UoM from the Recommendation 20 code list.

Data Type	Measurement (numeric & UoM qualifier)
GDSN Required	OPTIONAL

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- clinicalSizeValue. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

This GUDID attribute is a measurement attribute specifying the clinical measure of the device. This attribute is a numeric value and an associated Unit of Measure (UoM) qualifier. The UoM is a code from the UN Recommendation 20 Code List. The Data Pools will convert the UN Rec 20 code to the applicable code for the GUDID if needed. For the GUDID, the data pools will populate the numeric value in the GUDID attribute Size Value and the UoM qualifier in the GUDID attribute Size Unit of Measure.

For example, for a 16 gauge needle the value is 16 and the UoM is H79, for a 20 cc syringe the value is 20 and the UoM is CQM

This attribute is part of a repeatable class of clinical attributes for the device containing the Size Type, Size Value and Size Unit of Measure for the device's clinical size.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but can not be edited or deleted.

52. Size Unit of Measure

FDA GUDID

Description	The unit of measure associated with each clinically relevant size.
Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Can add after Grace Period, but cannot delete or edit.
Required?	1..* Required if Size is provided
Data Type & Length	Code List
Entry List of Values (LOV)	UCUM list of allowable values
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Temporary population until final GDSN deployment-

clinicalSizeUoM

Definition- The value to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user. For example 16 gauge for a needle, or 200 cc for a syringe. Carries a UoM from the Recommendation 20 code list.

Data Type	Code List (UoM qualifier)
GDSN Required	OPTIONAL
Final Deployment Attribute Name	clinicalSizeValue

Definition – The value to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user. For example 16 gauge for a needle, or 200 cc for a syringe. Carries a UoM from the Recommendation 20 code list.

Data Type	Measurement (numeric & UoM qualifier)
GDSN Required	OPTIONAL

Population Guidance (below)

This attribute has a temporary attribute (AVP) in GDSN- clinicalSizeValueUoM. It will be deployed into the GDSN Schema in 2016-17 into a final solution.

This GUDID attribute is a code list attribute specifying the clinical size unit of measure for the device's clinical size value. This attribute is a numeric value and an associated Unit of Measure (UoM) qualifier. The UoM is a code from the UN Recommendation 20 Code List. The Data Pools will convert the UN Rec 20 code to the applicable code for the GUDID if needed. For the GUDID, the data pools will populate the numeric value in the GUDID attribute Value and the UoM qualifier in the GUDID attribute Unit of Measure.

For example, for a 16 gauge needle the value is 16 and the UoM is H79, for a 20 cc syringe the value is 20 and the UoM is CQM

This attribute is part of a repeatable class of clinical attributes for the device containing the Size Type, Size Value and Size Unit of Measure for the device's clinical size.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but can not be edited or deleted.

53. Size Type Text

FDA GUDID

Description	Additional undefined device size not represented in the GUDID clinically relevant size list.
Data Entry Notes	Enter size type text in addition to units.
Edit Rules After Grace Period	Can add after Grace Period, but cannot delete or edit.
Required?	0..* Not Required
Data Type & Length	Alphanumeric (including symbols) (1-200 characters)
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Temporary population until final GDSN deployment-

clinicalSizeText

Definition When the clinicalSizeType is coded as "other", this is the text used to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user.

Data Type	Text (1-200 characters)
GDSN Required	OPTIONAL
Final Deployment Attribute Name	clinicalSizeText

Definition When the clinicalSizeType is coded as "other", this is the text used to denote the dimensional size which is clinically relevant for the use of the trade item by the clinical user.

Data Type	Text (1-200 characters)
GDSN Required	OPTIONAL

Population Guidance (below)

This attribute provides a value for this attribute when the GDSN attribute clinicalSizeType is required to be populated when a value of “OTHER” or “DEVICE_SIZE_TEXT,_SPECIFY” is published in the GDSN attribute clinicalSizeType. This is free text field and should only be used if the clinical size can not be specified using specific values in the Clinical Size Type Code List.

This attribute is part of a repeatable class of clinical attributes for the device containing the Size Type, Size Value and Size Unit of Measure for the device’s clinical size.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be added but can not be edited or deleted.

Storage Type

FDA GUDID

Description - Indicates storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure.

Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Can edit, add, or delete after Grace Period.
Required?	0..* Not Required, Required if Storage and Handling is provided
Data Type & Length	Code List

Entry List of Values (LOV) – CV for Storage Conditions- Storage environment temperature; Storage environment humidity; Storage environment atmospheric pressure; Handling environment temperature; Handling environment humidity; Handling environment atmospheric pressure

New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name- LOGICAL POPULATION- (Logical value based on the attribute (single or pair) chosen to be populated for the device.)

The list of applicable attributes are:

Current Attributes

Attribute Name-

a. storageHandlingTemperatureMaximum

b. storageHandlingTemperatureMinimum

c. storageHandlingHumidityMaximum

d. storageHandlingHumidityMinimum

e. transportationMaximumTemperature

f. transportationMinimumTemperature

Definition

a. The maximum temperature at which the trade item can be stored. This uses a measurement consisting of a unit of measure and a value.

b. The minimum temperature at which the trade item can be stored. This uses a measurement consisting of a unit of measure and a value.

c. The maximum humidity in percentages that the goods should be stored in.

d. The minimum humidity in percentages that the goods should be stored in.

e. The maximum temperature that a trade item can be held at during transport as defined by the manufacturer without affecting product safety or quality.

f. The minimum temperature that a trade item can be held below during transport as defined by the manufacturer without affecting product safety or quality.

Temporary Attributes

Attribute Name

a. storageEnvironmentAtmosphericPressureMaximum

b. storageEnvironmentAtmosphericPressureMinimum

c. transportationEnvironmentAtmosphericPressMaximum

d. transportationEnvironmentAtmosphericPressMinimum

e. transportationMaximumHumidityMaximum

f. transportationMaximumHumidityMinimum

Definition

a. The maximum atmospheric pressure in which the item should be stored to remain usable. This value is the value above which the trade item should not be subjected.

b. The minimum atmospheric pressure in which the item should be stored to remain usable. This value is the value below which the trade item should not be subjected.

c. The maximum atmospheric pressure in which the item should be transported to remain usable. This value is the value above which the trade item should not be subjected.

d. The minimum atmospheric pressure in which the item should be transported to remain usable. This value is the value below which the trade item should not be subjected.

e. The maximum humidity in percentages in which the trade items should be transported.

f. The minimum humidity in percentages in which the trade items should be transported.

Data Type	Measurement
GDSN Required	OPTIONAL

Population Guidance (below)

The GDSN attributes are pairs of attributes with a minimum and a maximum value. This provides a range of applicability for the device for that temperature/humidity/pressure pair. The applicable storage type can be derived from the attribute name.

For the GUDID, the GDSN attributes with “maximum” in their name will map the numeric value into the GUDID attribute High Value. The GDSN attributes with “minimum” in their name will map the numeric value into the GUDID attribute Low Value.

The following grid maps the GUDID code value for Storage Type to the applicable GDSN Attributes:

GUDID Storage Type Code	GDSN Attributes	
Storage environment temperature	storageHandlingTemperatureMaximum; storageHandlingTemperatureMinimum	
Storage environment humidity	storageHandlingHumidityMaximum; storageHandlingHumidityMinimum	
Storage environment atmospheric pressure	storageEnvironmentAtmosphericPressureMaximum; storageEnvironmentAtmosphericPressureMinimum	AVP
Handling environment temperature	transportationMaximumTemperature; transportationMinimumTemperature	
Handling environment humidity	transportationMaximumHumidityMaximum; transportationMaximumHumidityMinimum	AVP
Handling environment atmospheric pressure	transportationEnvironmentAtmosphericPressMaximum; transportationEnvironmentAtmosphericPressMinimum	AVP

Some devices have a temperature, humidity, or pressure range (High/Max and Low/Min values). Some have a greater than or less than value and others have a single or recommended value. Population of all possibilities can be handled in the GDSN and the GUDID using the following chart:

Information Type Available	Populated In	Value
Range of Lowest to Highest	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Highest Value
Less Than a Value	Minimum or Low Values Field	Leave Null (provide no value)
	Maximum or High Values Field	Highest Value
Greater Than a Value	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Leave Null (provide no value)
Single or Recommended Value	Minimum or Low Values Field	Single/Same Value populated in both fields
	Maximum or High Values Field	

54. Low Value

FDA GUDID

Description — Indicates the low value for storage and handling requirements.

Data Entry Notes — Must enter a Low Value and/or High Value if entering a Storage and Handling Type

Edit Rules After Grace Period — Can edit, add, or delete after Grace Period.

Required?	0..* Not Required, Required if Storage and Handling is provided
Data Type & Length	Numeric (1-6 digits)
Entry List of Values (LOV)	N/A
New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name LOGICAL POPULATION- (Logical value based on the attribute (single or pair) chosen to be populated for the device.)

The list of applicable attributes are:

Current Attributes

Attribute Name

storageHandlingTemperatureMinimum

storageHandlingHumidityMinimum

ttransportationMinimumTemperature

Definition

The minimum temperature at which the trade item can be stored. This uses a measurement consisting of a unit of measure and a value.

The minimum humidity in percentages that the goods should be stored in.

The minimum temperature that a trade item can be held below during transport as defined by the manufacturer without affecting product safety or quality.

Temporary Attributes

Attribute Name

a. storageEnvironmentAtmosphericPressureMinimum
b. transportationEnvironmentAtmosphericPressMinimum
c. transportationMaximumHumidityMinimum

Definition

a. The minimum atmospheric pressure in which the item should be stored to remain usable. This value is the value below which the trade item should not be subjected.
b. The minimum atmospheric pressure in which the item should be transported to remain usable. This value is the value below which the trade item should not be subjected.
c. The minimum humidity in percentages in which the trade items should be transported.

Data Type Measurement

GDSN Required OPTIONAL

Population Guidance (below)

The GDSN attributes are pairs of attributes with a minimum and a maximum value. This provides a range of applicability for the device for that temperature/humidity/pressure pair. The applicable storage type can be derived from the attribute name.

For the GUDID, the GDSN attributes with “maximum” in their name will map the numeric value into the GUDID attribute High Value. The GDSN attributes with “minimum” in their name will map the numeric value into the GUDID attribute Low Value.

The following grid maps the GUDID code value for Storage Type to the applicable GDSN Attributes:

GUDID Storage Type Code	GDSN Attributes	
Storage environment temperature	storageHandlingTemperatureMaximum; storageHandlingTemperatureMinimum	
Storage environment humidity	storageHandlingHumidityMaximum; storageHandlingHumidityMinimum	
Storage environment atmospheric pressure	storageEnvironmentAtmosphericPressureMaximum; storageEnvironmentAtmosphericPressureMinimum	AVP
Handling environment temperature	transportationMaximumTemperature; transportationMinimumTemperature	
Handling environment humidity	transportationMaximumHumidityMaximum; transportationMaximumHumidityMinimum	AVP
Handling environment atmospheric pressure	transportationEnvironmentAtmosphericPressMaximum; transportationEnvironmentAtmosphericPressMinimum	AVP

Some devices have a temperature, humidity, or pressure range (High/Max and Low/Min values). Some have a greater than or less than value and others have a single or recommended value. Population of all possibilities can be handled in the GDSN and the GUDID using the following chart.

Information Type Available	Populated In	Value
Range of Lowest to Highest	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Highest Value
Less Than a Value	Minimum or Low Values Field	Leave Null (provide no value)
	Maximum or High Values Field	Highest Value
Greater Than a Value	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Leave Null (provide no value)
Single or Recommended Value	Minimum or Low Values Field	Single/Same Value populated in both fields
	Maximum or High Values Field	

55. High Value

FDA GUDID

Description - Indicates storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure.

Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Can edit, add, or delete after Grace Period.
Required?	0..* Not Required, Required if Storage and Handling is provided
Data Type & Length	Code List

Entry List of Values (LOV) – CV for Storage Conditions- Storage environment temperature; Storage environment humidity; Storage environment atmospheric pressure; Handling environment temperature; Handling environment humidity; Handling environment atmospheric pressure

New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name- LOGICAL POPULATION- (Logical value based on the attribute (single or pair) chosen to be populated for the device.) The list of applicable attributes are:

Current Attributes

Attribute Name-

a. storageHandlingTemperatureMaximum

b. storageHandlingHumidityMaximum

c. transportationMaximumTemperature

Definition

a. The maximum temperature at which the trade item can be stored. This uses a measurement consisting of a unit of measure and a value.

b. The maximum humidity in percentages that the goods should be stored in.

c. The maximum temperature that a trade item can be held at during transport as defined by the manufacturer without affecting product safety or quality.

Temporary Attributes

Attribute Name

a. storageEnvironmentAtmosphericPressureMaximum

b. transportationEnvironmentAtmosphericPressMaximum

c. transportationMaximumHumidityMaximum

Definition

a. The maximum atmospheric pressure in which the item should be stored to remain usable. This value is the value above which the trade item should not be subjected.

b. The maximum atmospheric pressure in which the item should be transported to remain usable. This value is the value above which the trade item should not be subjected.

c. The maximum humidity in percentages in which the trade items should be transported.

Data Type	Measurement
GDSN Required	OPTIONAL

Population Guidance (below)

The GDSN attributes are pairs of attributes with a minimum and a maximum value. This provides a range of applicability for the device for that temperature/humidity/pressure pair. The applicable storage type can be derived from the attribute name.

For the GUDID, the GDSN attributes with “maximum” in their name will map the numeric value into the GUDID attribute High Value. The GDSN attributes with “minimum” in their name will map the numeric value into the GUDID attribute Low Value.

The following grid maps the GUDID code value for Storage Type to the applicable GDSN Attributes.

GUDID Storage Type Code	GDSN Attributes	
Storage environment temperature	storageHandlingTemperatureMaximum; storageHandlingTemperatureMinimum	
Storage environment humidity	storageHandlingHumidityMaximum; storageHandlingHumidityMinimum	
Storage environment atmospheric pressure	storageEnvironmentAtmosphericPressureMaximum; storageEnvironmentAtmosphericPressureMinimum	AVP
Handling environment temperature	transportationMaximumTemperature; transportationMinimumTemperature	
Handling environment humidity	transportationMaximumHumidityMaximum; transportationMaximumHumidityMinimum	AVP
Handling environment atmospheric pressure	transportationEnvironmentAtmosphericPressMaximum; transportationEnvironmentAtmosphericPressMinimum	AVP

Some devices have a temperature, humidity, or pressure range (High/Max and Low/Min values). Some have a greater than or less than value and other have a single or recommended value. Population of all possibilities can be handled in the GDSN and the GUDID using the following chart.

Information Type Available	Populated In	Value
Range of Lowest to Highest	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Highest Value
Less Than a Value	Minimum or Low Values Field	Leave Null (provide no value)
	Maximum or High Values Field	Highest Value
Greater Than a Value	Minimum or Low Values Field	Lowest Value
	Maximum or High Values Field	Leave Null (provide no value)
Single or Recommended Value	Minimum or Low Values Field	Single/Same Value populated in both fields
	Maximum or High Values Field	

56. Special Storage Conditions

FDA GUDID

Description	Indicates any special storage requirements for the product.
Data Entry Notes	Can enter alphanumeric with symbols
Edit Rules After Grace Period	Can edit, add, or delete after Grace Period.
Required?	0..* Not Required, Required if Special Storage Condition Text selected
Data Type & Length	Alphanumeric (1-200 Characters)
Entry List of Values (LOV)	
New DI Trigger?	NO

Public/Private Status	Public

GS1 GDSN

Attribute Name	consumerUsageStorageInstructions

Definition- Expresses in text the consumer storage and usage instructions of a product which are normally held on the label or accompanying the product. This information may or may not be labelled on the pack. Instructions may refer to a suggested storage temperature, a specific storage requirement or a reference to environment or duration. Examples include: “Refrigerate After Opening”, “Consume within 4 days” “Keep Out Of Direct Sunlight” ,”Store at an Ambient Temperature”, “Store in a Clean, Cool, Dry Place”, “Store Away From Sunlight, Strong Odours and Chemicals”, “Keep in a Clean, Cool, Dry and Odourless Place Away From Direct Sunlight and Freezing Temperatures”, “Keep in a Clean, Cool, Dry and Odourless Place Away From Direct Sunlight”, “Before opening store at + 5°C+ 30°C”, “After Opening Keep Refrigerated (+5°C) and Consume Within 48 hours”, “Drink Chilled”, “Store in a Cool Dry Place”, “Refrigerate After Opening. Can Be Kept in the Fridge For 3 Months”.

Data Type	Text (Language qualified) (1-1000 characters)
GDSN Required	OPTIONAL

Population Guidance (below)

This attribute can be populated with any special storage, transportation, or handling instructions as deemed necessary by the supplier/manufacturer.

57. Device Packaged as Sterile

FDA GUDID

Description	Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.
Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Cannot edit after Grace Period.
Required?	1..1 Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Attribute Name	initialManufacturerSterilisation

LOGICAL POPULATION (Logical BOOLEAN value of TRUE from the population of any value in initialManufacturerSterilisation)

Definition- Type(s) of sterilisation that may have been performed by the manufacturer if a trade item is sterile when it comes from the manufacturer. Sterilisation refers to any process that effectively kills or eliminates transmissible agents (such as fungi; bacteria; viruses; prions and spore forms etc.) from a surface; equipment; foods; medications; or biological culture medium. Some methods of sterilisation are through the application of heat; radiation; and ethylene.

Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This GDSN attribute is a code list. If a value is published in GDSN, it indicates that the device is sold as being sterile. Therefore if a value is published in the GDSN attribute initial ManufacturerSterilization, then a value of “TRUE” will be populated in the GUDID. If no value is published in GDSN, then a value of “FALSE” will be populated in the GUDID.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

58. Requires Sterilization Prior to Use

FDA GUDID

Description	Indicates that the device requires sterilization prior to use.
Data Entry Notes	Choose a value from the drop down. (Webtool)
Edit Rules After Grace Period	Cannot edit after Grace Period.
Required?	1..1 Required
Data Type & Length	Boolean
Entry List of Values (LOV)	Yes/No
New DI Trigger?	YES
Public/Private Status	Public

GS1 GDSN

Attribute Name LOGICAL POPULATION- (Logical BOOLEAN value of TRUE from the population of any value in initialSterilisationPriorToUse)

Definition	N/A
Data Type	N/A
GDSN Required	OPTIONAL

Population Guidance (below)

The GDSN attribute initialSterilirilizationPriorToUse is a code list indicating the type(s) of sterilization which should be performed on a device prior to use. Population of a value for this attribute signifies that the device is not sterile and that the Provider does need to sterilize it prior to use using the method populated. If a code value is published in the GDSN, then a value of “TRUE” will be populated in the GUDID. If no value is published in GDSN, then a value of “FALSE” will be populated in the GUDID.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can not be changed. Many of the data elements are locked and can no longer be edited.

59. Sterilization Method

FDA GUDID

Description - Indicates the method(s) of sterilization that can be used for this device.

Data Entry Notes	Choose a value from the drop down. (Webtool)

Edit Rules After Grace Period	Can edit, add or delete after Grace Period only if 'Yes' was selected for 'Requires Sterilization Prior to Use' before Grace Period. Cannot add Sterilization Methods after Grace Period if 'No' was selected for 'Requires Sterilization Prior to Use' before Grace Period.
Required?	1..* Required if 'Requires Sterilization Prior to Use' is marked 'Yes'
Data Type & Length	N/A

Entry List of Values (LOV) – Sterilization Methods LOV- Chlorine Dioxide, Dry Heat, Ethylene Oxide, High Intensity Light or Pulse Light, Hydrogen Peroxide, Microwave Radiation, Moist Heat or Steam, Ozone, Peracetic Acid, Radiation, Radiation, Sound Waves, Ultraviolet Light

New DI Trigger?	NO
Public/Private Status	Public

GS1 GDSN

Attribute Name	initialSterilisationPriorToUse

Definition- This is an indication of the type(s) of sterilisation that is required to be completed by a healthcare provider prior to initial use of the healthcare trade item. Sterilisation refers to any process that effectively kills or eliminates transmissible agents (such as fungi; bacteria; viruses; prions and spore forms etc.) from a surface; equipment; foods; medications; or biological culture medium. Some methods of sterilisation are through the application of heat; radiation; and ethylene.

Data Type	Code List
GDSN Required	OPTIONAL

Population Guidance (below)

This GDSN attribute is a code list of the type(s) of sterilization, which can be performed on a device by the Provider prior to use. When this attribute is published, a value of “TRUE” will be populated for the GUDID attribute Requires Sterilization Prior to Use.

Once published, a 7-day grace period begins. During the grace period, most attributes can be edited. After the grace period ends on day 8, this attribute can be edited, but only under certain circumstances. See Edit Rules After Grace Period for more details

7. References

- For more information on UDI at a global level refer to *http://www.gs1.org/healthcare/udi*
- For more information on the IMDRF refer to *http://www.imdrf.org/*
- For more information on the U.S. FDA UDI refer to *http://www.gs1us.org/industries/healthcare/gs1-healthcare-us/fda-udi*
- For more information on the GDSN refer to *http://www.gs1.org/gdsn*
- For more information on GS1 Healthcare refer to *http://www.gs1.org/healthcare*
- For country support contact your local GS1 Member Organisation *http://www.gs1.org/contact*