Medical Devices Data Bank

User Manual
DM Manufacturer Profile

Version 1.1
February 2008

SUMMARY

1 Introduction

This document contains the user manual of the "Banca Dati Dispositivi Medici" system functions.

The "Banca Dati Dispositivi Medici" System, provides features used to record the Class I, IIa/b and III Medical Devices; available on the national market, purchasable by the NHS as well as the information regarding the Marketing of the Devices. The moment in which the objects have been registered as available for purchase, or that is, when the relative data to enable the payment transaction, the devices result as registered on the index.
The System was realised in accordance and complying with the following regulations:

- Directive 93/42/EEC;
- Legislative decree 24 February 1997, no.46, modified and integrated by the legislative decree of February 25 1998 no.95 and September 8th 200 No.332 (implemented regulation in Italy from the EEC directive)
- Article 57 of the 27th December 2002 law No.289(financial law 2003)

For the purpose of using the functionality of the IDM(index of medical devices) System. Four types of users were defined and given access to the system.

1. "FABBRICANTEDM"
2. "UFFICIDGFDM"
3. "REGIONEDM",
4. "AZIENDESANITARIEDM".

The "FABBRICANTEDM" users can register DM data, activate the publication process, while awaiting the validation of the DM, and register it on the index.
The "UFFICIDGFDM" users can consult valid DM data along with its publications, or request the correction of the same.
The"REGIONEDM" and "AZIENDESANITARIEDM" users can look at Medical Devices data after the pubblication process and registration into the index..

1.1 Definitions and Glossary

1.1.1 Glossary of terms

Terms	Definitions
Consolidamento	This operation checks registered data regarding a DM or an assembled device.
Validazione	A key action in which the user, who has registered the DM data, signs for the data inserted into the system and makes them visible to the Ministry for Health.
Pubblicazione	The publication of data is the way in which the Ministry makes DMs, previously passed over from the Manufacturer, available for a subsequent publication on the data portal.
Mandatario	Individual or legal entity within the European Union territory who after being expressively assigned by the manufacturer, acts on behalf of the Manufacturer and can thus be consulted by the national authority concerned and by Community bodies in place of the Manufacturer.
Responsabile dell'immissione in commercio	Individual or legal entity who in the case that the Manufacturer is not appointed within the Community is obliged to keep the relative documentation available to the authorities of the merchandise.
Altro soggetto delegato dal fabbricante	Individual or legal entity who is delegated by the Manufacturer in order to register the DMs in to the system (e.g. The distributor/Wholesaler)
Iscrizione al repertorio	A process in which the data regarding fee payment transaction is inserted.

1.1.2 Acronyms

Acronyms	Definitions
SSN	Local Health Board
CUB	Unique Board for Devices
CND	National Classification of Medical Devices
DGFDM	General Management of Medicines and Medical Devices
DM	Medical Device

GMDN	Global Medical Device Nomenclature
MdS	Ministry of Health
NSIS	New Health Information System

2 DM MANUFACTURER Profile

2.1 Access to the System

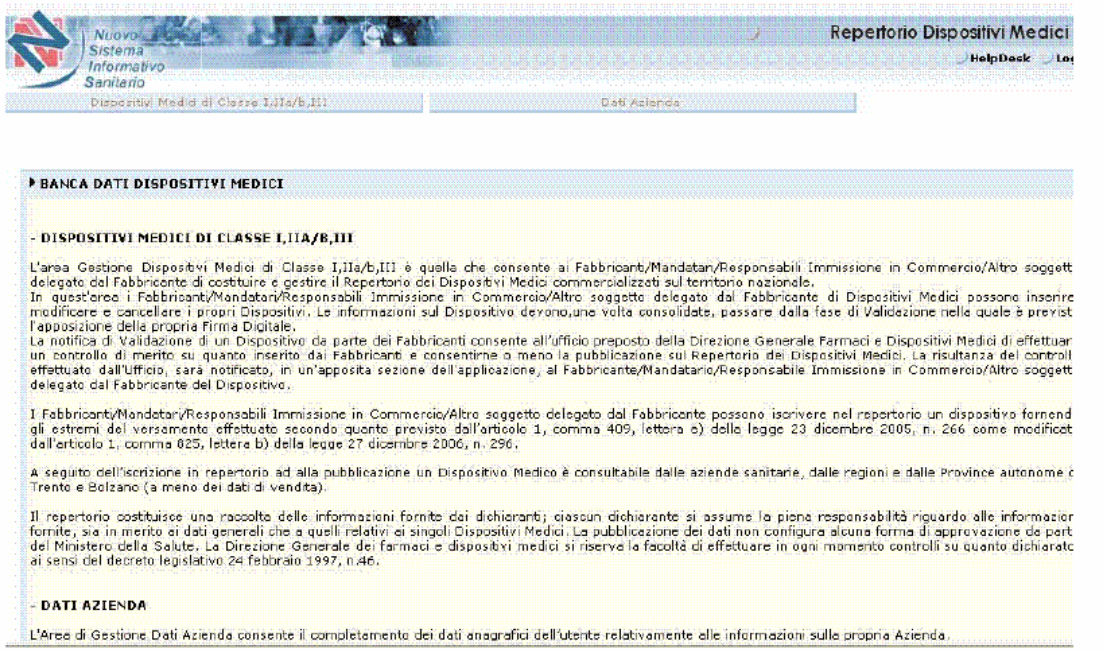
In order to access the system it is necessary to refer back to the MdS web site www.ministerosalute.it

2.2 Function areas of the System

Once logged on, the user may access the functions of the system

The system is contains two specific functionality areas:

1. Class I, II a/b and III Medical Devices
2. Company Data



These areas display different functions depending on the user connected.

2.2.1 Functional Area of “Dispositivi medici di classe I, IIa/b, III”

The Functional Area of “Dispositivi medici di classe I, IIa/b, III” contains the administration functions of the purchase and validation process of the Classified medical devices.
In this area the Manufacturers, Mandate Holders and Marketing directors of the Medical Devices can insert, edit and delete their pertaining devices. Once the information on the device has been confirmed it must go through the validation process in which the user must provide his electronic signature. When the Manufacturers announce the validation of a device this allows the head of pharmaceuticals and the executive management department of a device to carry out a credit/merit inspection on what the Manufacturers have inserted and whether or not to allow their publication on the DM index. The outcome of the inspection carried out by the department will then be communicated to the manufacturers/Mandate Holders/Marketing directors/other individuals delegated by the Manufacturer’s device.

Manufacturers/Mandate Holders/Marketing directors/other individuals delegated by the Manufacturer’s device can register a device in the index providing the essential details of the payment transaction in accordance with article1, paragraph 409, letter e) of the 27 December 2006 Law No.266 as modified by Art.1, Para. 825, letter b) of the December 27 Law No.296

Having registered a Medical Device on the index and published it, it is available to be consulted by the autonomous regional and provincial Health Boards of Trento and Bolzano (except for the sales data).

The index is made up of a collection of information provided by Manufacturers; each Manufacturer accepts full responsibility for the information supplied, both for the General data and data regarding single Medical Devices. The publication of this data does not represent any form of approval by the Ministry for Health. The General Administrative Office of pharmaceutical products and medical devices reserves the right to carry out inspections at any time as stated according to the provisions of the Legislative Decree February 24th 1997, No.46.

Within the confines of this functional area, the following functions are present:

1. **Dispositivo Medico (DM)**
2. **Sistemi e kit assemblati (c.2 Art.12)**
3. **Attività**
4. **Caricamento DM da file**
5. **Certificati CE**

The "Dispositivo Medico (DM)" feature is both visible by "FABBRICANTEDM" users, as well as "UFFICIDGFDM" users. This functionality allows:

- The "FABBRICANTEDM" users to have access to the management functions of the information relative to their own devices (insert, edit or delete) and to validate the same, by inserting their electronic signature and lastly making them visible to the head department of the GMFMD
- The "UFFICIDGFDM" users can access the consultation function of the DM that have at least been Validated.

The "Assembled systems and kits" feature (para.2 Art.12.) is visible to both "FABBRICANTEDM" users and "UFFICIDGFDM" users. The menu options allow both users to consult the announcements relative to validation/publication activity entered in reference to the DM.

The "Upload DM from file" option is only visible to "FABBRICANTEDM" users and permits the loading of data of one or more DM from the file and also permits the consultation of any errors that may have occurred in the uploading process itself.

The functionality "Certificati CE" is visible only to the users with "FABBRICANTEDM" role and allows to manage the EC certificates issued by the Organizations notified for the medical devices.

2.2.2 "Company data" Function area.

The "Company Data" functional area contains functions that allow the user to complete his personal data; regarding information about their own company as well as that of other companies represented by the individual, in order to register the data of the DM.

Within the confines of this function area, the following functions are present:

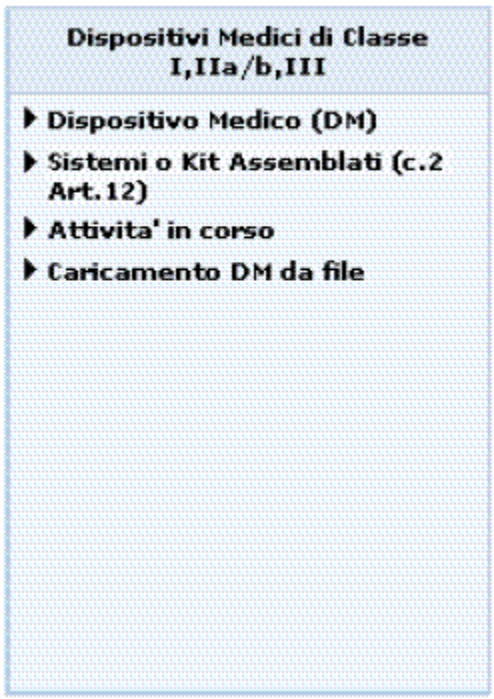
1. General Data Stated

2. Declaration of other Manufacturers

The first time a user accesses the system, he must run the “General Data Statement” feature, in order to complete the Manufacturing Company’s information.
The “Other Manufacturer’s Statements” indicates the companies represented by the user and the data of their registered DM.

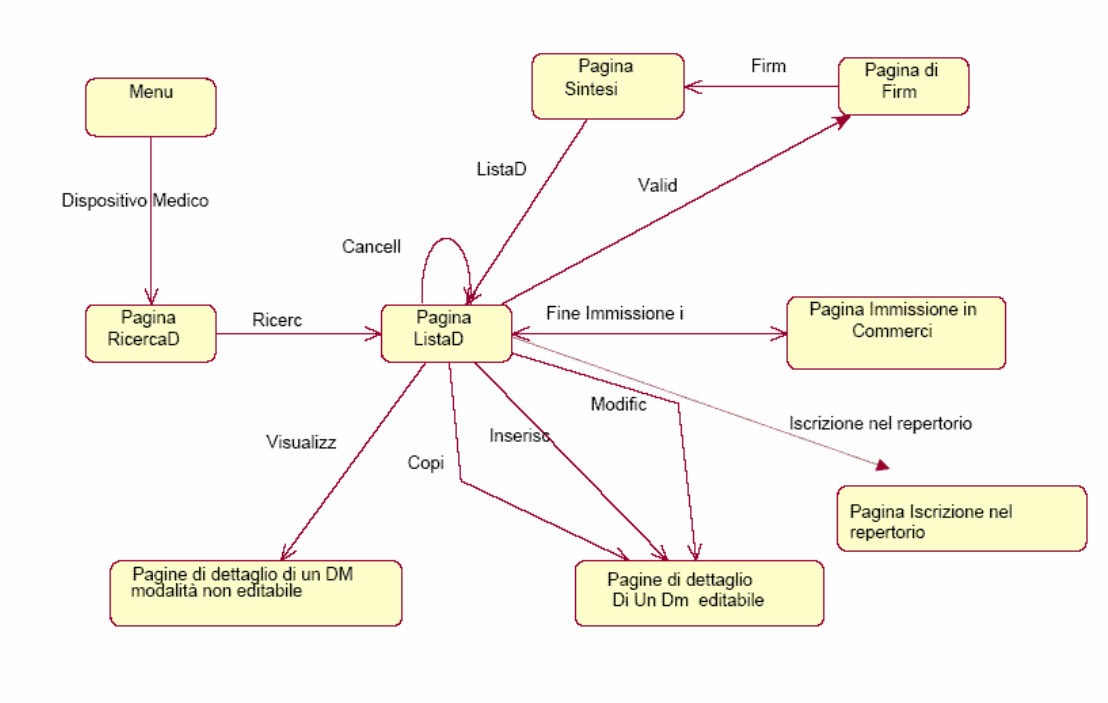
2.3 Detailed description of the “Dispositivo Medico di Classe I, IIa/b and III” Functional area

After having accessed the “Dispositivo medico di Classe I, IIa/b and III” Functional area on the left-hand side of the page, the menu appears for the available functions in the area. This menu will offer different options depending on the profile of the user connected.
In particular, the “FABBRICANTEDM” user will see all of the options on the menu.



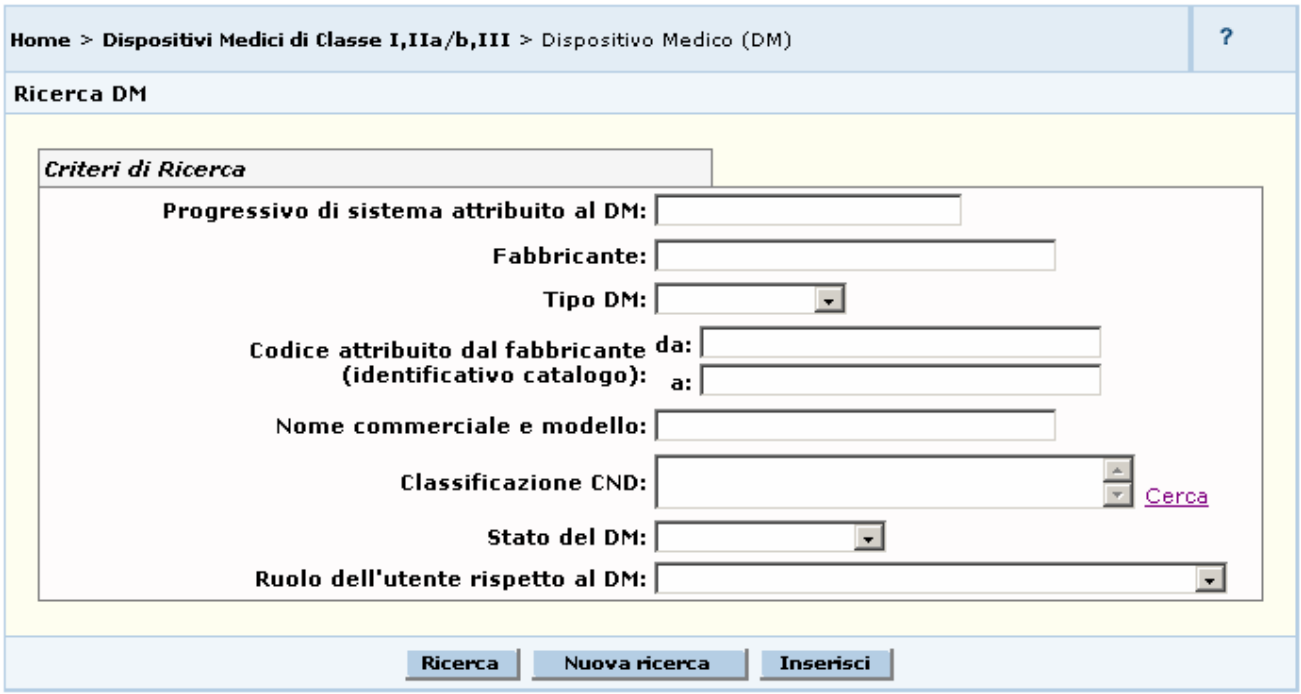
2.3.1 "Dispositivo Medico (DM)" Menu option

Screen flowcharts



2.3.1.1 DM Search

Having clicked on "Dispositivo Medico (DM)" on the menu, a page appears which allows the user to define the search criteria of the DM registered on the system. To activate a search on the DM, the user must define at least one margin.
From this page, the user may also access the page containing the general data of a DM.



Details of DM search Fields

Field Name	Description
Progressivo di sistema attribuito al DM	Option to serch a Medical Device by its identification number assigned by the system during registration into the database.
Fabbricante	Option to specify the name (or the beginning) of the Manufacturer of the DM
Tipo DM	Option to indicate the type of classified DM, choosing between: -Device -System -Kit
Codice attribuito dal fabbricante (identicativo catalogo) da/a	Option to indicate the range of codes which includes the product code assigned to the DM by the Manufacturer.
Nome commerciale e modello	Option to specify the commercial name (or beginning) of the DM
Classificazione CND	Option to run a search using the National classification of the DM. This field cannot be edited. To select a classified CND and click on the search link; “Cerca”. A look-up will then open where the user has the option to search a CND by code or by description or part thereof.
Stato del DM	Option to serch a Medical Device by its current status into the system (“In lavorazione”, “Consolidato”, “Validato”, “Pubblicato”).
Ruolo dell’utente rispetto al DM	Optino to serach a Medical Device by the role carried out by the user with respect to thatl Medical Device (“Fabbricante”, “Mandatario”, “Responsabile dell’immissione in commercio”, “Altro soggetto delegato

	dal fabbricante")

Operations available

Action	Description	Page Name
Inserisci	Allows access to the DM general data entry page	Pagine di dettaglio di un DM in Modalità editabile
Ricerca	Activates a search on the basis of the criteria inserted	Pagina Lista DM
Nuova ricerca	Clears the search criteria previously defined	Same

2.3.1.2 Visualisation of DM List

When at least one of the search criteria has been entered, and the user has clicked the "Ricerca" button, the search is activated and a list of DM corresponding to the criteria specified comes up on screen.
For every DM, the following information is displayed:

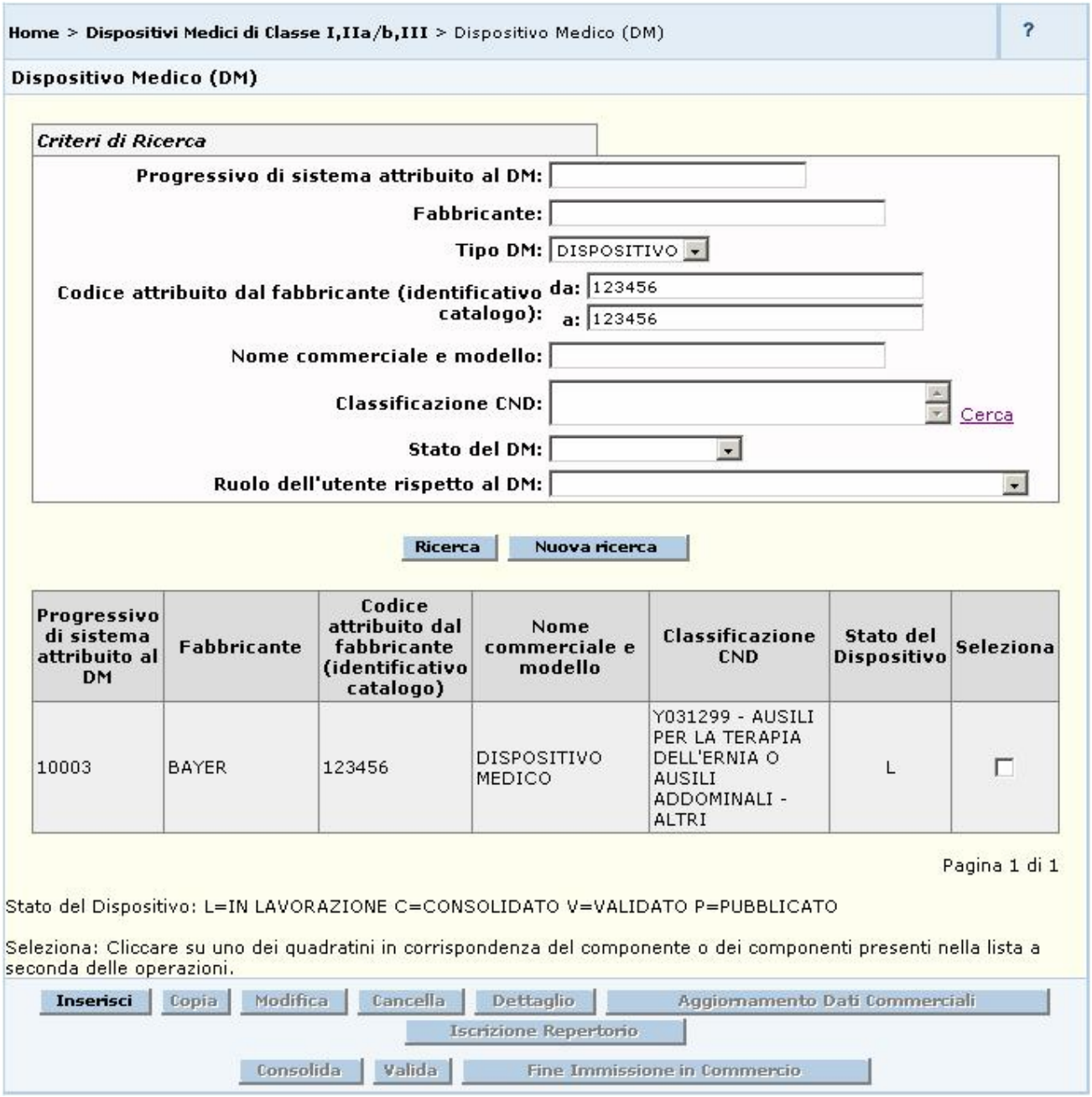
- Consecutive identification number assigned to the DM by the system
- The manufacturer
- The product code assigned to the DM by the manufacturer
- The Commercial name of the DM
- The CND classification
- The status of the DM

If /R appears next to the consecutive number assigned to the DM by the system, it means that the DM has been registered on the index.

The DM list changes, not only on the basis of the criteria entered but also on the basis of the user connected;

If the user is the Manufacturer/Mandate holder/Marketing Director, he will only see the DM originating from the company he represents, regardless of its status in the database; he can put the following actions into operation from this page:

- Run a new search
- Insert a new DM by copying an existing DM.
- Edit a DM that's status is "In Lavorazione"
- Delete a DM that's status is "In Lavorazione"
- Insert the issue date of the placement of a DM on the market marked "Validato" or "Pubblicato"
- Register a DM on the index by inserting the payment data of the fee due for a DM in "Validato" or "Pubblicato" status
- Validate a DM
- Consult the details of a DM



DM Search Detail Fields

Field Name	Description
Progressivo di sistema attribuito al DM	Option to serch a Medical Device by its identification number assigned during registration into the database.
Fabbricante	Option to specify the name (or the beginning) of the Manufacturer of the DM
Tipo DM	Option to indicate the type of classified DM, choosing between: -Device -System -Kit

Codice attribuito dal fabbricante (identicativo catalogo) da/a	Option to indicate the range of codes which includes the product code assigned to the DM by the Manufacturer.
Nome commerciale e modello	Option to specify the commercial name (or beginning) of the DM
Classificazione CND	Option to run a search using the National classification of the DM. This field cannot be edited. To select a classified CND and click on the search link; "Cerca". A look-up will then open where the user has the option to search a CND by code or by description or part thereof.
Stato del DM	Option to serch a Medical Device by its current status into the system ("In lavorazione", "Consolidato", "Validato", "Pubblicato").
Ruolo dell'utente rispetto al DM	Optino to serach a Medical Device by the role carried out by the user with respect to that Medical Device ("Fabbricante", "Mandatario", "Responsabile dell'immissione in commercio", "Altro soggetto delegato dal fabbricante")

DM List Detail Fields

Field Name	**Description**
Progressivo di sistema attributo al DM	Unique identification number assigned to each DM in the **database**. If /R appears next to the consecutive number assigned to the DM by the system, it means that the DM has been registered on the index.
Fabbricante	Corporate name of the DM Manufacturing Company
Codice attribuito dal fabbricante (identicativo catalogo) da/a	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Nome commerciale e modello	Commercial name or model of the DM
Classificazione CND	CND Classification assigned to the DM
Stato nella base dati	The status of the DM in the database. It can change status in the following order: • L: Processing • V: Valid • P: Published • C: Confirmed

Operations available

Action	**Description**	**Page Name**
Ricerca	Activates a search based on the criteria inserted	Same
Nuova	Clears the search criteria previously defined	Same

ricerca		
Inserisci	Allows access to the DM general data entry page	Pagine di dettaglio di un DM in Modalità editabile
Modifica	Allows the user to access the pages containing details of the DM selected and to edit those details (only visible to "FABBRICANTEDM" users	Pagine di dettaglio di un DM in Modalità editabile
Cancella	Allows the user to delete the DM selected (only visible to "FABBRICANTEDM" users	Same
Consolida	Allows the approval of a DM in "In Lavorazione" status. The "Consolida" action brings up the page with the list of DM in the approval phase; specifying whether the process has been activated or not. The outcome of the process, if negative, will be marked on the activity list or will change it's status to C, that is "Consolidato"	Pagina di dettaglio sullo stato dell'avvio del processo
Valida	Activates the signature page through which Option to validate one or more DM with "Consildato" status. Changing the status of the DM does not occur simultaneously with the "Valida" action.	Pagina di firma
Copia	Allows the user to copy a DM in order to insert a new DM which has the same characteristics as the copied DM	Pagine di dettaglio di un DM in Modalità editabile
Fine immissione in commercio	Grants access to the off-market data entry page of the DM selected	Pagina di fine immissione in commercio
Iscrizione al repertorio	Allows the user to enter the payment details on the data entry page	Pagina iscrizione nel repertorio
Visualizza	Allows the user to enter the details of the DM selected onto the detail page in read-only form	Pagina di dettaglio di un DM in Modalità non editabile

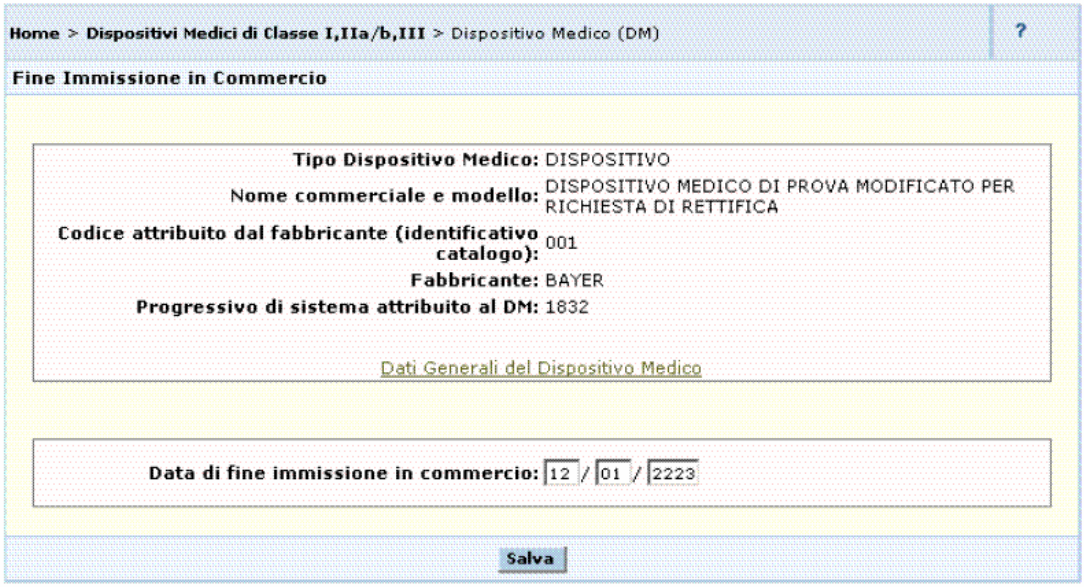
2.3.1.3 Off-Market

This page allows the user to insert/edit the off-market date of a "Valida" or Pubblicato" DM.

To insert the off-market date of a DM, the user must proceed as follows:
1. Run the search for the DM (from the "Dispositivo Medico (DM)" option on the menu)
2. Select a "Valido" or "Pubblicato" DM and click on "Fine immisione in commercio"
3. Insert the off-market date and confirm the operation by clicking on the "Salva" button

If the off-market date has been indicated, it will appear in the general data page in reference to the DM.

In the upper part of the page, the principle data of the DM are displayed as well as the "Dati Generali del Dipositivo Medico" link which opens the page containing the general data of the DM.



Detail Fields

Field Name	Description
Tipo Dispositivo Medico	Type of DM. There are three types: - Device - System - Kit
Nome commerciale e modello	Commercial name or model of the DM
Codice attribuito dal fabbricante (identicativo catalogo) da/a	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Fabbricante	Corporate name of the DM Manufacturing Company
Progressivo di sistema attributo al DM	Unique identification number assigned to each DM in the **database**. If /R appears next to the consecutive number assigned to the DM by the system, it means that the DM has been registered on the index.
Data fine immissione in commercio	Off-market date of DM.

Operations available

Action	**Description**	**Page name**
Salva	Saves the information inserted	Pagina Lista DM

2.3.1.4 DM Approval page

This page allows the user to view the DM which have begun the process of data approval from the DMs selected. The approval activates a series of congruity and consistency tests on the released data and any errors discovered are noted on the activity list page. If no errors are found, the status of the DM changes to "Consolidato" and it is therefore possible to activate the validation of the device by means of a electronic signature.

DM List in approval phase Detail Fields

Field Name	Description
Progressivo di sistema attribuito al DM	Unique identification number assigned to each DM in index.
Fabbricante	Corporate name of the DM Manufacturing Company
Codice attribuito dal fabbricante (identicativo catalogo)	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Nome commerciale e modello	Commercial name or model of the DM
Stato processo validazione	The status of the process. It can change status in the following order: • Initiated • Uninitiated

Operations available

Action	Description	Page Name
Vai alla Lista attività	Allows user to return to the activity list	Lista Attività

2.3.1.5 DM Signature Page

This page allows the user, who has inserted the specific DM, to digitally sign, in order to validate that same device.

The user must possess a Smart Card in order to sign digitally.

To validate a DM, a user must proceed as follows:

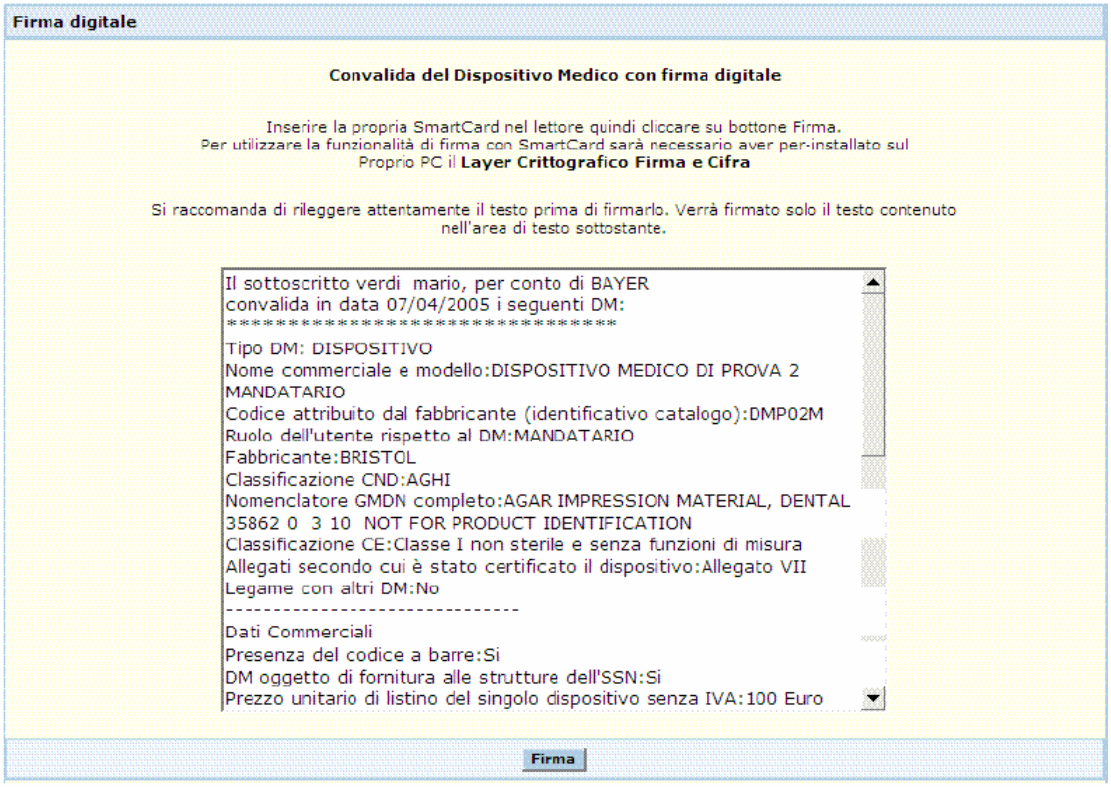
1. Run the search for the DM (from the “Dispositivo Medico (DM)” option on the menu)
2. Select a DM marked “in lavorazione” and click on the “Validazione button
3. Click the “Firma” button
4. Insert the PIN code in the space provided

Before digitally signing, the user must be sure to read the text displayed on the signature page that runs:

“Il sottoscritto…(name and surname of user connected), per conto di…(name of company for whom the user acts as manufacturer) convalida il DISPOSITIVO…(commercial name of device) con identicativo catologo…in data …(today’s date)”

In order for the validation to run smoothly and the request for release to arrive at the DGFDM department, the DM must have the following:

1. All required general data and all of the relevant documentation present.
2. The indication of other DMs which are required in order for this DM to function, when “Legami con altri DM” has been marked “Si” in its general data.
3. Indication, of systems and kits covered by in Para.3, Art.12 of at least two components, one of which, by necessity, must be a DM not marked with the CE logo.
4. Publication of all components in reference to the systems or kits covered by Para3. Art12.



Operations available:

Action	Description	Page Name
Firma	Allows the user to validate a DM after having entered their PIN in the space provided	PaginaSintesiDM

2.3.1.6 PaginaSintesiDM

This page displays the principle information on the DMs which have been validated by the user in read-only mode.

DM list in approval phase Field Details

Field Name	**Description**
Progressivo di sistema attributo al DM	Unique identification number assigned to each DM in index.
Fabbricante	Corporate name of the DM Manufacturing Company
Codice attribuito dal fabbricante (identicativo catalogo)	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Nome commerciale e modello	Commercial name or model of the DM
Stato processo validazione	The status of the process. It can change status in the following order: • Initiated • Not Initiated

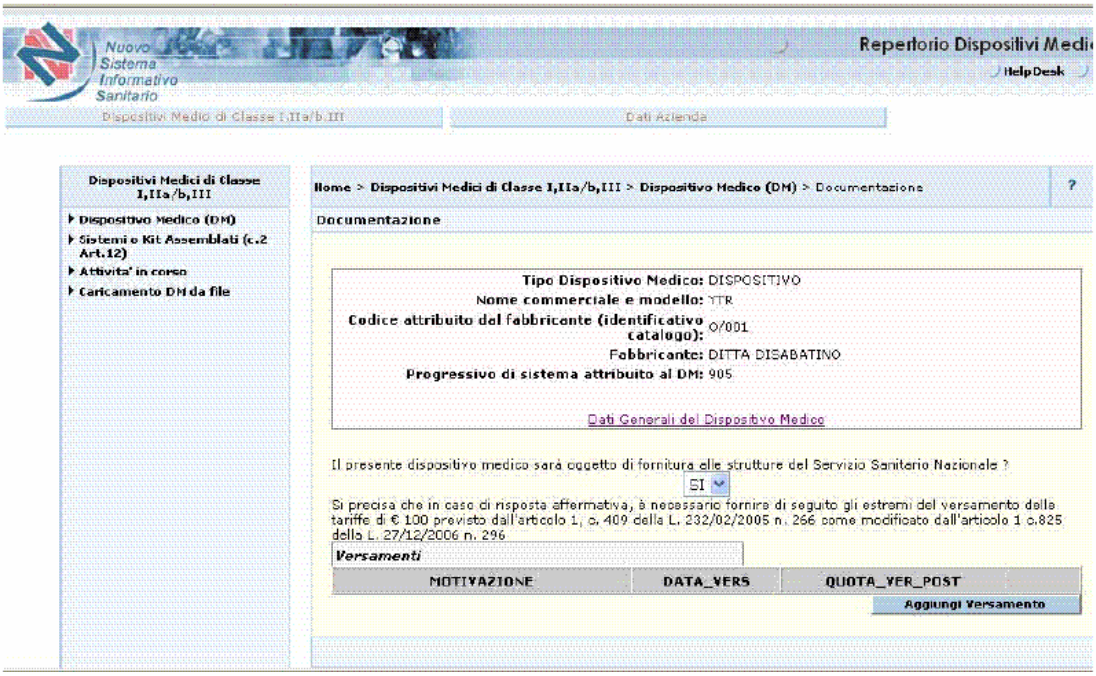
Operations available

Action	Description	Page Name
Vai alla Lista attività	Allows user to return to the activity list	Lista Attività

2.3.1.7 Registration on the Index

In order to register a DM on the index, the user must proceed as follows:

1. Run the DM search (from the "Dispositivo Medico (DM)" option in the menu, specifying the search criteria and then clicking on "Ricerca") ;
2. Select a DM in "Validato" or "Pubblicato" status
3. Click on "Iscrizione nel repertorio"



This page allows the user to register a device on the index supplying the co-ordinates of the payment made, as in accordance with Article 1, Paragraph 409, e) of the December 23 2005 Law No.266 and as modified by Article1, Paragraph 825, b) of the December 27 2006 Law No. 296

All of the DMs registered on the index may be viewed exclusively by the A.S.L and by the business. This action has two steps:

The user expresses the desire to insert the DM in the index.
The user inserts the payment details.

Only after having done this, can the system register the device as part of the index.

The index contains a collection of information supplied by Manufacturers; each Manufacturer assumes full responsibility for the information supplied, be it for the general data as for that regarding single Medical Devices. The publication of data does not represent the approval of the Health Department in any form. The executive management of pharmaceutical products and medical devices reserve the right to carry out an inspection on what has been declared, at any time, as laid out in the legislative decree February24 1997, No.46

In order to register a DM inserted in the databank onto the index, it must be either a valid or published status.

Detail Fields

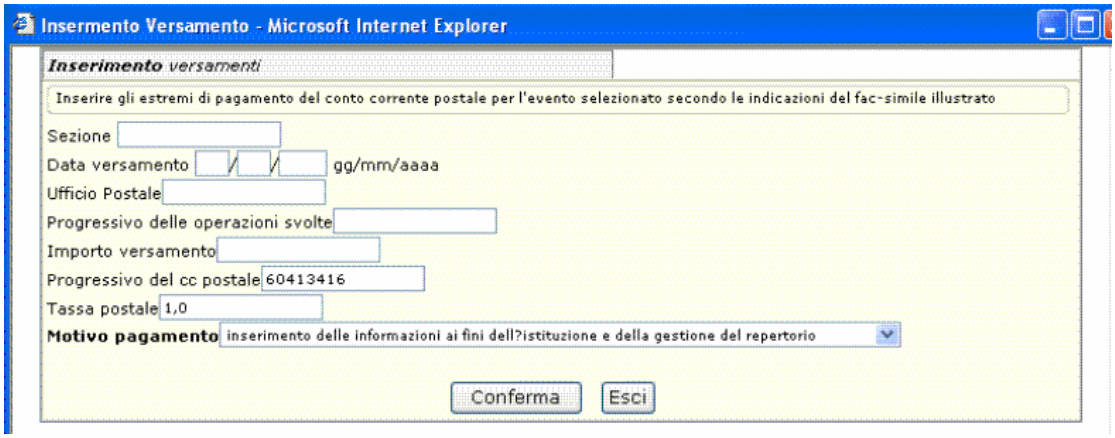
Field Name	Description
Tipo Dispositivo Medico	Type of DM. Three types exist: - Device - System - Kit
Nome commerciale e modello	Commercial name or model of the DM
Codice attribuito dal fabbricante (identicativo catalogo)	Code attributed to the DM by the manufacturing company (better known as the identification catalogue)
Fabbricante	Corporate name of the DM Manufacturing Company
Flag iscrizione repertorio	A flag which indicates whether or not the user wishes to place their DM on the index, and thus make it available to the S.S.N The default setting is “No” If the user selects “Si”, therefore expressing their wish to register their DM on the index, the data cannot be edited

Operations available

Action	**Description**	**Page Name**
Aggiungi Versamento	Allows the user to add a payment for a DM. This action may be executed more than once	Finestra Pop up

Detail Fields

Motivo pagamento	Reason for making the payment
Data Versamento	The date in which the transaction was made
Quota_ver_post_	Amount paid



Detail Fields

Sezione	Department of office where the payment was made
Data Versamento	The date in which the payment was made
Post Office	Post Office co-ordinates where the transaction was performed
Progressivo delle operazione svolte	Id number of the transaction carried out
Importo versamento	The amount deposited
Progressivo del cc postale	Account number of postal checking account.
Tassa postale	Postal tax paid for the transaction carried out
Motivo pagamento	Reason for the payment

Operations available

Action	**Description**	**Page Name**
Conferma	Saves the information inserted	Pagina Iscrizione nel repertorio
Esci	Closes the window without saving the actions carried out by the user	Pagina Iscrizione nel repertorio

2.3.1.8 DM Insertion

In order to insert a new DM, the user must proceed as follows:

4. Run the DM search (from the “Dispositivo Medico (DM)” option in the menu, specifying the search parameters and then clicking on “Ricerca”) after having verified the DM you wish to insert is not already on the index

5. Click on the “Inserisci” button
6. Insert the relative information relative to “Dati Generali” and confirm the action by clicking on the “Salva” button

7. Insert the specific information that corresponds to the menu options that will then be accessible after the “Dati Generali” has been saved using the “Salva” button

2.3.1.8.1 DM detail page for insertion/editing

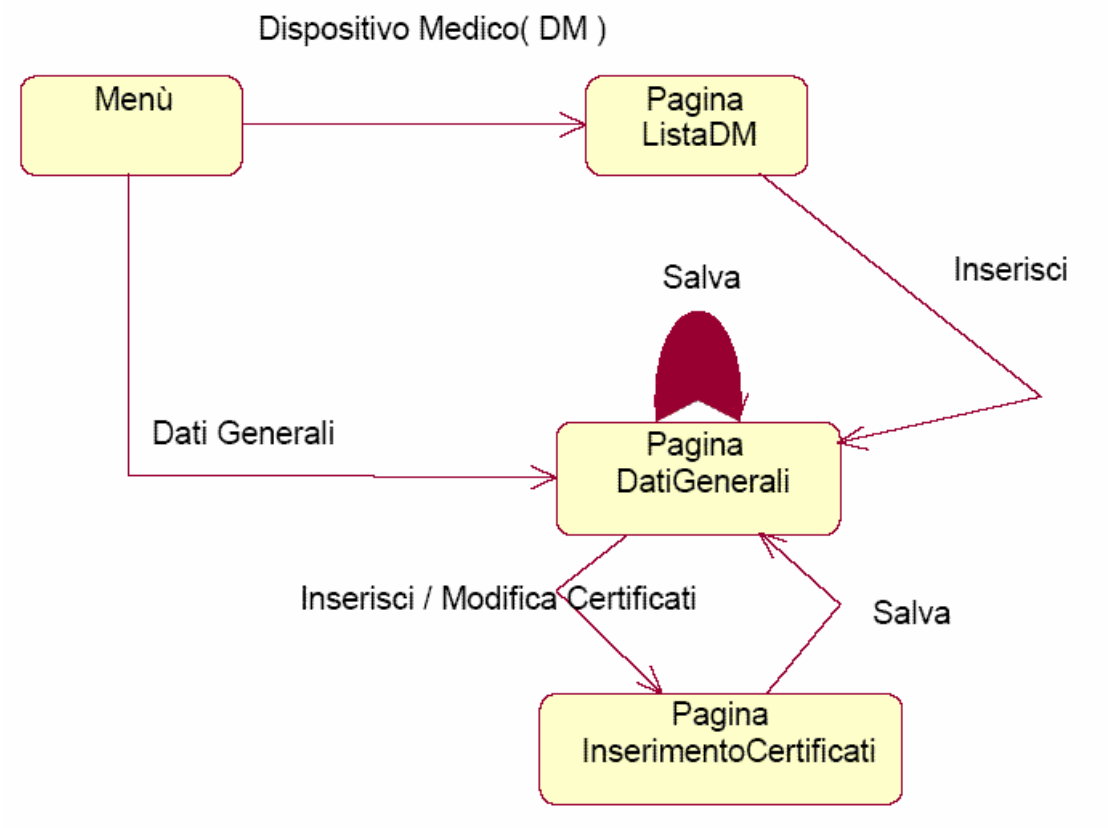
The detail pages of a DM in read-only mode are only accessible by “FABBRICANTEDM” users and allow them to insert new DM and also to edit a DM selected from the “Pagina Lista DM”.

The detail pages are:

1. General Data
2. Specifications
3. Documentation
4. Commercial Data
5. System and kit settings (Para.3 Art.12)
6. Any other DM necessary for its function

In particular if it’s in insertion mode, the General Data page will become activated once the user clicks on the “Inserici” button on the list page and only after the data has been saved on the “Pagina Dati Generali” will the options on the menu become available and allow the user access to other pages.
If it is in edit mode, the General Data page will become available following the selection of a DM from the list and the menu option will become visible simultaneously to allow access to other pages.

2.3.1.8.1.1 General Data



In order to insert a new DM, the manufacturer/mandate holder/marketing director must first specify, general data of the DM, in order to then go on to register other information (specifications, commercial data, documentation, any other DM necessary for its function, system or kit components (in the case of a system or kit) from the relevant page accessible through the corresponding menu options.

The General Data page allows the user to insert general data regarding a DM. The general data of a DM are subdivided in four areas:

- General data
- Classification data
- Certification data
- Links with other DM

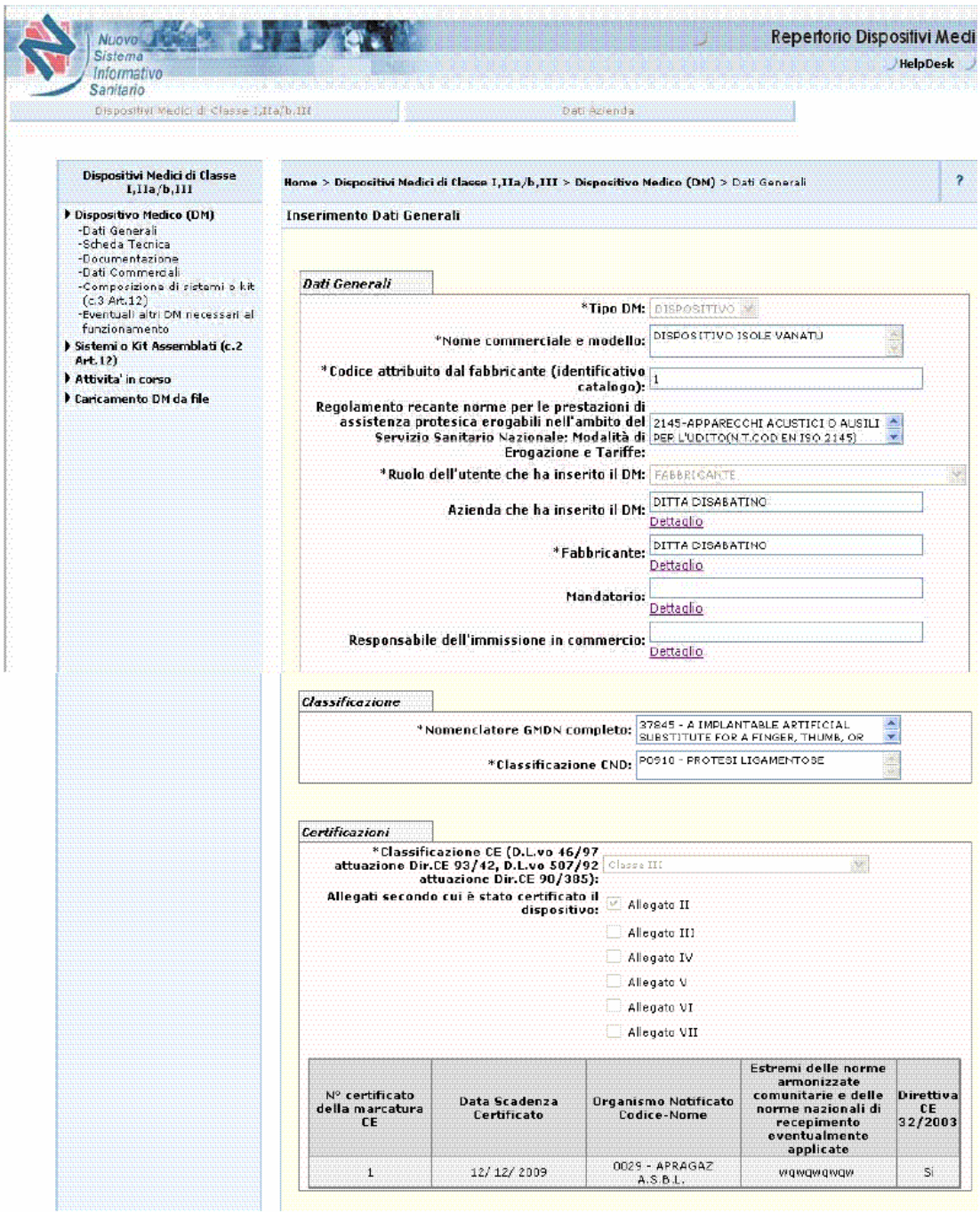
It will be necessary to consult the General Data page of a DM in the following cases:

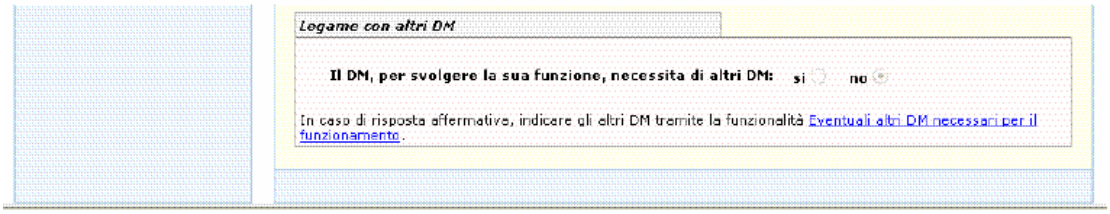
- In the insertion phase of the DM
- In the editing phase of the DM
- In the insertion phase of the DM, by coping a DM that already exists

The user can also connect different DM on this page which are interdependent for operational purposes by clicking on the “Eventuali altri DM necessari per il

funzionamento", after having saved the "Dati Generali" by clicking on the "Salva" button.

Page Name: General Data Page





General DM Data Field Detail

Field Name	Description
General Data	
Tipo DM	Indication of the type of classified Medical Device. The following types of DM exist: - Device - System - Kit
Nome commerciale e modello	Denomination of the DM, as given by the Manufacturer
Ulteriori Nomi commerciali del DM	List of commercial names subsequently assigned to the DM
Codice attribuito dal fabbricante (identicativo catalogo)	Specific code attributed to the DM by the manufacturer.
Regolamento recante norme per le prestazioni di assistenza protesica erogabili nell'ambito del Servizio Sanitario Nazionale Mobilità di Erogazione e Tariffe	Name of DM according to the nomenclature charges in force
Ruolo dell'utente rispetto al DM	Indicates the role carried out by the user with respect to the DM. The user can adopt the following roles: - Manufacturer - Mandate Holder - Marketing Director - Other individual delegated by the Manufacturer
Fabb./Man./Resp.Imm.Comm./Altr.Sogg.Del.Fabbr.:	Indicates the Manufacturing company/Mandate Holder/Marketing Director/Other individual from the Manufacturer of the DM
Fabbricante	Name of the Manufacturer of the DM. If the user has selected the role of Manufacturer of the DM, the system therefore selects the Manufacturer that has been previously stipulated by the user in the "Gestione Dati Azienda" feature If the user has selected a role other than fabbricante, he can select the Manufacturer clicking on the "Cerca" link; a look-up will open where Option to search for and select a Manufacturer.
Mandatario	Name of Mandate Holder of DM. If the user has selected the role of Mandate holder, regarding the DM, the system will automatically display the user's company, as

	Mandate holder in the "Gestione Dati Azienda" feature. He can select the Mandate holder by clicking on the "Cerca" link; a look-up will open where the user has the option to search for and select a Mandate holder. The mandate holder may be selected only if the Manufacturer is registered in a non EU country.
Responsabile dell'immissione in commercio	Name of Marketing Director. If the user has selected the role of Marketing Director of the DM, the system therefore selects the Marketing Director that has been previously stipulated by the user in the "Gestione Dati Azienda" feature. If the user has selected a role other than Marketing Director, he can select the Marketing Director clicking on the "Cerca" link; a look-up will open where the user has the option to search for and select a Marketing Director. The Marketing Director may be selected only if the Marketing Director is registered in a non EU country.
Progressivo di sistema attributo al DM	Unique identification number assigned to each DM by the system. This field is not editable and is visible only when editing the DM.
Already Registered	State that the registration has already been carried out in accordance with Legislative Decree 46/1997
Classifications	
Nomenclatore GMDN completo	Indicates the classification according to the GMDN(Global Medical Device Nomenclature) of the DM. This field cannot be edited. To select classification according to the GMDN, it is necessary to click on the "Cerca" link; a look-up will open with which the user can search such a classification by code and description (or part there of). The system will automatically indicate whether the GMDN chosen is linked to only one unique CND code or multiple codes.
Classificazione CND	Indication of the National classification of the DM. This field is not editable. The system automatically completes the field, following the choice of a GMDN associated with one unique CND. Alternaively it is also possible to specify a CND code unconnected with the GMDN code, selecting a specific check in the same look-up
Certifications	
Classificazione CE (D.L.vo 46/97 attuazione Dir. CE 93/42; D.L.vo 517/92; attuazione Dir. CE 90/385	Indication of the EC classification of the DM. The EC classification can adopt the following principles: - Class I with measurement functions - Class I non sterile and or measurement functions - Class I sterile - Class I sterile with measurement functions - Class IIa - Class IIb - Class III - Active implant devices
Allegati secondi cui è stato marcato il	Indication of the attachments according to which the device has been marked.

dispositivo	The following inspections are initiated: - in the case of Class I sterile I DM with measurement functions, Attachments VII and IV or Attachments VII and V or Attachments VII and VI must be selected - in the case of Class I DM, Attachment VII must be selected - in the case of Class IIa, Attachment II or Attachment VII together with either Attachment IV,V or VI must be selected - in the case of Class IIb, Attachment II or Attachment III together with either Attachment IV, V or VI must be selected - in the case of Class III, Attachment II or Attachment III together with either Attachment IV or V must be selected - in the case of a Active implant device, Attachment II or Attachments III together with either IV,V or VI must be selected
Links to other DM	
The DM is dependent on other DM in order to operate	Indication of whether or not the DM is dependant on other DM in order to operate

Operations Available:

Action	**Description**	**Page name**
Salva	Saves inserted information	Same
Cancella Certificato	Deletes the association with the EC Certificate selected	Same
Inserisci Certificato	Allows access to the page of the EC Certificates association	Pagina Inserimento Certificati
Aggiungi	Allows user to add a field which the user can insert an additional commercial name	Same
Rimuovi	Allows the removal of additional commercial name selected	Same

Page Name: Certificates

This page is displayed in look-up format and allows the user to search and associate the EC certificates with the DM. This feature is activated by clicking on the “Inserisci Certificato” button found on the “Dati Generali” page.
The certificates which can be inserted are those registered in the section management of the certificates, issued to the same manufacturer of the device.
In correspondence to every DM it is necessary to insert at least one certificate.

Certificates with EC stamp Detail Fields

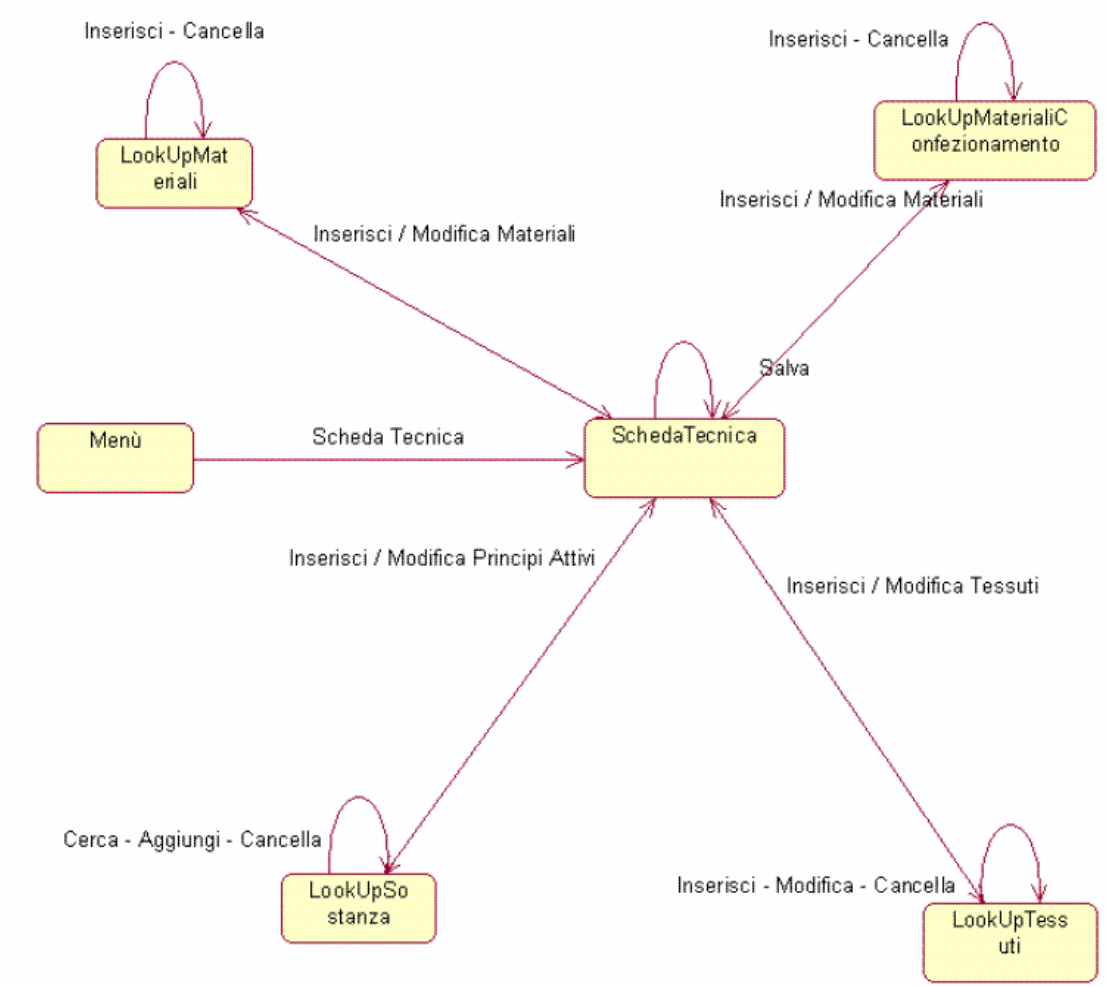
Field Name	Description
N Certificato della marcatura CE	Identification number of the EC stamp
Data Scadenza Certificato	Expiry date of Certificate
Organismo notificato -Codice - Nome	Indication of the code and name of the organisation notified. This field cannot be edited. To select the code of the organisation notified it is necessary to click on the “Cerca” link; a look-up will open which will allow the user to search for the notified Organisation by name and code
Estremi delle norme armonizzate comunitarie e delle norme nazionali di recepimento eventualmente applicate	Indication of the Essential details of the National and Community norms acknowledged during the fabrication of the DM
Direttiva CE 32/2003	States whether or not the certificate should be issued in compliance with EC Directive 32/2003

Operations available:

Action	**Description**	**Page name**
Ricerca	Activates a search on the basis of the criteria inserted	Same
Nuova	Clears the search criteria previously defined	Same

ricerca		
Conferma	Closes the look-up, inserts the certificate or the certificates selected adjourning the list of the certificates on general DM data page	Pagina Dati Generali
Annulla	Closes the look-up without saving the work done by user	Pagina Dati Generali

2.3.1.8.1.2 Specifications



Page Name: Specifications

The “Scheda Tecnica” page allows the user to insert/edit information on the technical data of a DM. The data of the specifications data sheet of a DM are subdivided in the following areas:

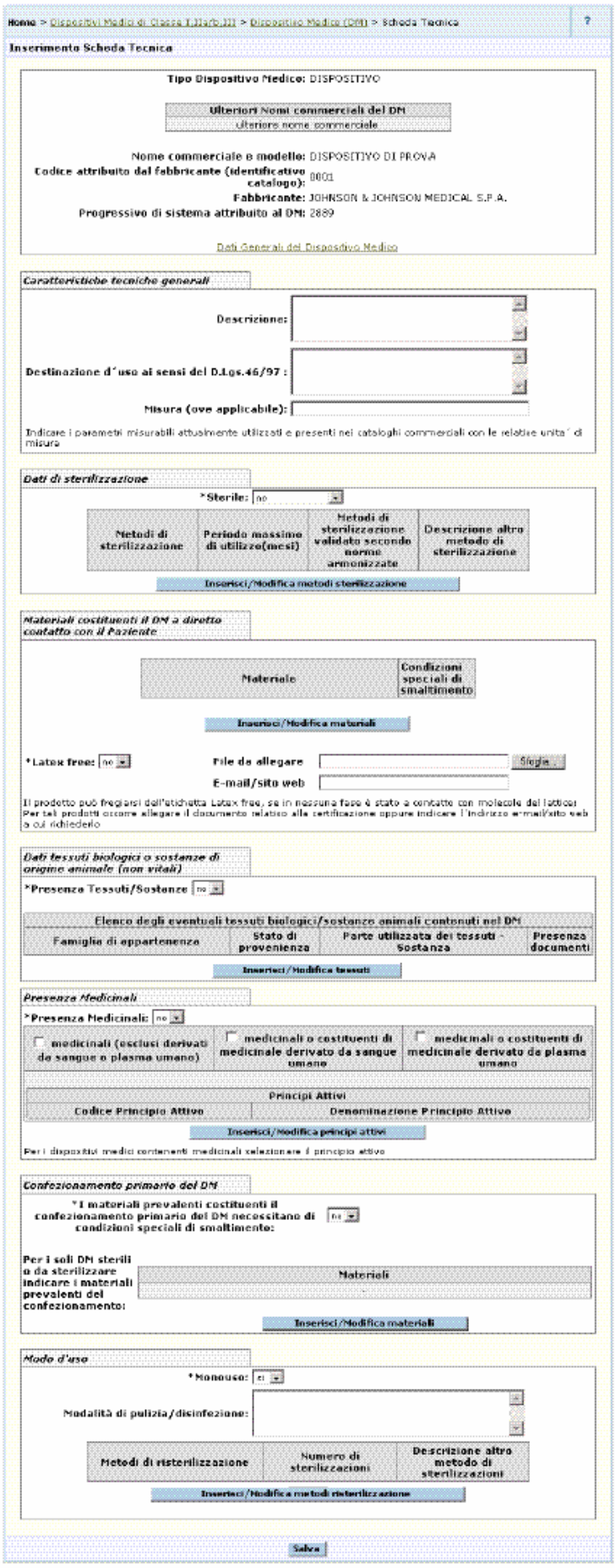
- General technical characteristics
- Date of sterilisation
- DM material that comes in direct contact with the patient (see relevant paragraph)
- Medicinal products present patient (see relevant paragraph)
- Primary packaging of DM patient (see relevant paragraph)
- Directions for use

The “Scheda Tecnica” page is accessible to users in the following cases:

- During the insertion phase of the DM after the registration of the data
- During the editing phase of the DM
- During the insertion phase of the DM by coping one that already exists in the system

While saving the data of the specifications data sheet, at least one material contained in the DM that comes in direct contact with the patient and can be pointed out as material contained in the primary packaging of the DM, must be indicated only if the label “Sterile” corresponds; being marked “Si”

In the upper part of the page the principle data of the DM are displayed; as well as the “Dati Generali del Dispositivo Medico” link, which allows the user to see the general data of the DM.


Home > Dispositivi Medici di Classe I,IIa/b,III > Dispositivo Medico (DM) > Scheda Tecnica
Inserimento Scheda Tecnica
Tipo Dispositivo Medico: DISPOSITIVO
Ulteriori Nomi commerciali del DM
Ulteriore nome commerciale
Nome commerciale e modello: DISPOSITIVO DI PROVA
Codice attribuito dal fabbricante (identificativo catalogo): 0001
Fabbricante: JOHNSON & JOHNSON MEDICAL S.P.A.
Progressivo di sistema attribuito al DM: 2889
Dati Generali del Dispositivo Medico
Caratteristiche tecniche generali
Descrizione:
Destinazione d'uso ai sensi del D.Lgs.46/97 :
Misura (ove applicabile):
Indicare i parametri misurabili attualmente utilizzati e presenti nei cataloghi commerciali con le relative unita' di misura
Dati di sterilizzazione
*Sterile: no
Metodi di sterilizzazione
Periodo massimo di utilizzo(mesi)
Metodi di sterilizzazione validato secondo norme armonizzate
Descrizione altro metodo di sterilizzazione
Inserisci/Modifica metodi sterilizzazione
Materiali costituenti il DM a diretto contatto con il Paziente
Materiale
Condizioni speciali di smaltimento
Inserisci/Modifica materiali
*Latex free: no
File da allegare
Sfoglia...
E-mail/sito web
Il prodotto può fregiarsi dell'etichetta Latex free, se in nessuna fase è stato a contatto con molecole del lattice? Per tali prodotti occorre allegare il documento relativo alla certificazione oppure indicare l'indirizzo e-mail/sito web a cui richiederlo
Dati tessuti biologici o sostanze di origine animale (non vitali)
*Presenza Tessuti/Sostanze no
Elenco degli eventuali tessuti biologici/sostanze animali contenuti nel DM
Famiglia di appartenenza
Stato di provenienza
Parte utilizzata dei tessuti - Sostanza
Presenza documenti
Inserisci/Modifica tessuti
Presenza Medicinali
*Presenza Medicinali: no
medicinali (esclusi derivati da sangue o plasma umano)
medicinali o costituenti di medicinale derivato da sangue umano
medicinali o costituenti di medicinale derivato da plasma umano
Principi Attivi
Codice Principio Attivo
Denominazione Principio Attivo
Inserisci/Modifica principi attivi
Per i dispositivi medici contenenti medicinali selezionare il principio attivo
Confezionamento primario del DM
*I materiali prevalenti costituenti il confezionamento primario del DM necessitano di condizioni speciali di smaltimento:
Per i soli DM sterili o da sterilizzare indicare i materiali prevalenti del confezionamento:
Materiali
Inserisci/Modifica materiali
Modo d'uso
*Monouso: si
Modalità di pulizia/disinfezione:
Metodi di risterilizzazione
Numero di sterilizzazioni
Descrizione altro metodo di sterilizzazioni
Inserisci/Modifica metodi risterilizzazione
Salva

Field Name	Description
General technical characteristics	
Descrizione	Description of the general technical characteristics of the DM
Destinazione d'uso ai sensi del D.Lgs.46/97	Intended use In accordance with the D.Lgs.46/97
Misura (ove applicabile)	Indication of the measurable criteria actually used and present in commercial catalogues with the corresponding unit of measurement of the DM
Sterilisation data	
Sterile	Indication of whether or not the DM is sterile
Metodo di sterilizzazione	Method used to sterilise the DM. This field is required if the “Sterile” field is marked “Si”
Se altro Metodo di sterilizzazione specificare	Description of the sterilisation method if it is not already present on the loaded list previously. This field is required if the “Metodo di sterilizzazione” field is marked “Altro”
Metodo di sterilizzazione validato secondo	The method of sterilisation can be validated: - according to the harmonised norms - other. This field is required if the “Sterile” field is marked “Si”
Periodo massimo di utilizzo	Maximum length of use of the DM. This field is required if the “Sterile” field is marked “Si”
Material contained in the DM that comes in direct contact with the Patient	
Latex free	Indication as to whether or not the DM contains latex.
Fila da allegare	File containing the Latex free certification. This field is required if in the “Latex free” field it was marked “Si”
E-mail/Sito web	Indication of email or web site where the Latex free certificate can be requested. This field is required if in the “Latex free” field it was marked “Si” This field is an alternative to the “File da allegare” field
Data of biological tissue or substances of animal origin (not vital)	
Presenza Tessuti/Sostanze	Indication of whether or not the DM contains Biological tissue/animal substances
Medicinal products Present	
Presenza Medicinali	Indication as to whether or not the DM contains medicinal products
Medicinali (esclusi derivati da sangue o plasma umano)	Indicates if there are medicines present in the DM (except for those derived from blood or human plasma). This field can be ticked only if it was marked “Si” in the “Presenza Medicinali” field
Medicinali o cosituenti di medicinale derivati da sangue umano	Indicates if there are medicines present in the DM derived from human blood). This field can be ticked only if it was marked “Si” in the “Presenza Medicinali” field
Medicinali o cosituenti di medicinale derivati	Indicates if there are medicines present in the DM derived from human plasma). This field can be ticked only if it was marked “Si” in the “Presenza

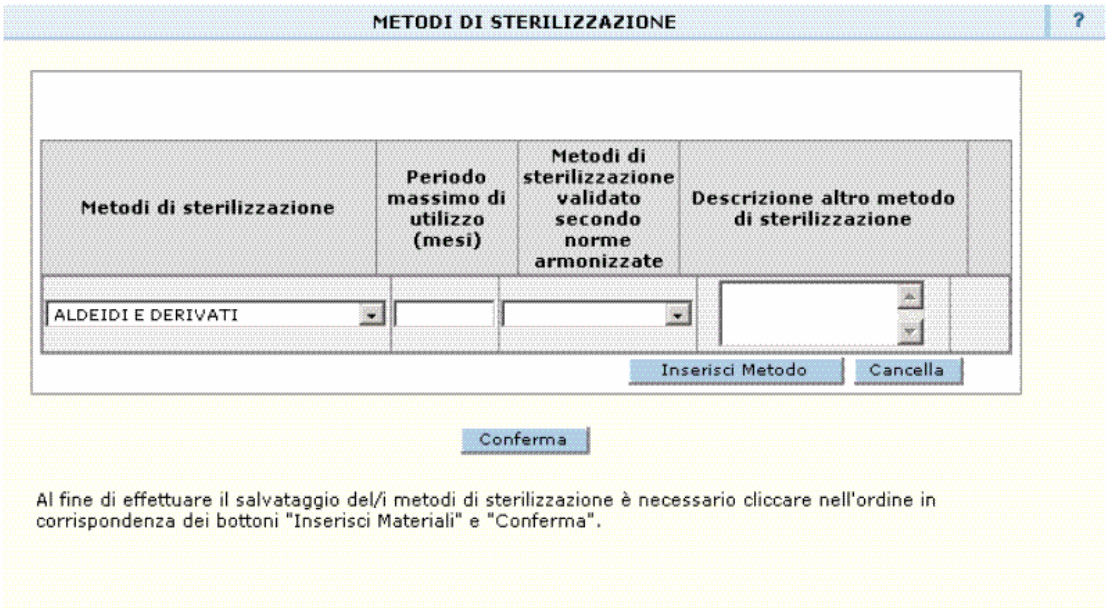
da plasma umano	Medicinali" field
Primary packaging of the DM	
I materiali prevalenti costituenti il confezionamento primario del DM necessitano di condizioni speciali di smaltimento	Indicates if the primary packaging of the DM must be disposed of in a specific manner
Directions for use	
Monouso	Indicates whether or not the DM is disposable
Metodo di risterilizzazione	Method used to re-sterilise the DM. This field is required if in the "Monouso" field it was marked "No"
Se altro Metodo di risterilizzazione, specificare	Description of method of re-sterilisation if it is not found on the previously loaded list. This field is required if in the "Metodo di Re-sterilizzazione" field it was marked "Other"
Modalità di pulizia/disinfezione	Method used to clean/disinfect the DM. This field is required if in the "Monouso" field it was marked "No"
Numero di sterilizzazione consentite(ove stabilito)	Maximum number of times it is permitted to sterilise a DM. This field is required if in the "Monouso" field it was marked "No"

Operations Available

Action	**Description**	**Page Name**
Salva	Saves the information inserted	Same
Inserisci/Modifica metodi sterilizzazione	Allows the user access to the administrative window of the sterilisation methods of a DM	LookUpMetodiSteril
Inserisci/Modifica materiali	Allows the user access to the administrative window of the Material contained in the DM	LookUpMateriali
Inserisci/Modifica Tessuti	Allows the user access to the administrative window of the biological tissues/animal substances contained in the DM	LookUpTessuti
Inserisci/Modifica i	Allows the user access to the administrative window of the Active ingredients contained in the DM	LookUpSostanze
Inserisci/Modifica material	Allows the user access to the administrative window of the primary packaging material contained in the DM	LookUpMateraliConfezionamento
Inserisci/Modifica metodo risterilizzazione	Allows the user access to the administrative window of the re-sterilisation methods of the DM	lookUpMetodiRisteril

Page Name: LookUpMetodiSteril

This page is displayed in look-up format and allows the user to insert and cancel methods of sterilisation of DM that come in direct contact with the patient. It is activated by clicking on the "Inserisci/Modifica metodi sterilizzazione" button which is found on the "Scheda Tecnica" page.
When saving the data on the specifications data sheet, it is required to indicate at least one method of sterilisation of the DM in the case that it has been marked as being sterile.



Methods of sterilisation of DM Detail Fields

Field Name	**Description**
Metodo di sterilizzazione	Method used to sterilise the DM. This field is required if the "Sterile" field is marked "Si"
Periodo massimo di utilizzo	Maximum length of use of the DM. This field is required if the "Sterile" field is marked "Si"
Metodo di sterilizzazione validato secondo	The method of sterilisation can be validated: - according to the harmonised norms - other. This field is required if the "Sterile" field is marked "Si"
Se altro metodo di sterilizzazione, specificare	Description of method of sterilisation if it is not found on the previously loaded list. This field is required if in the "Metodo di sterilizzazione" field it was marked "Other"

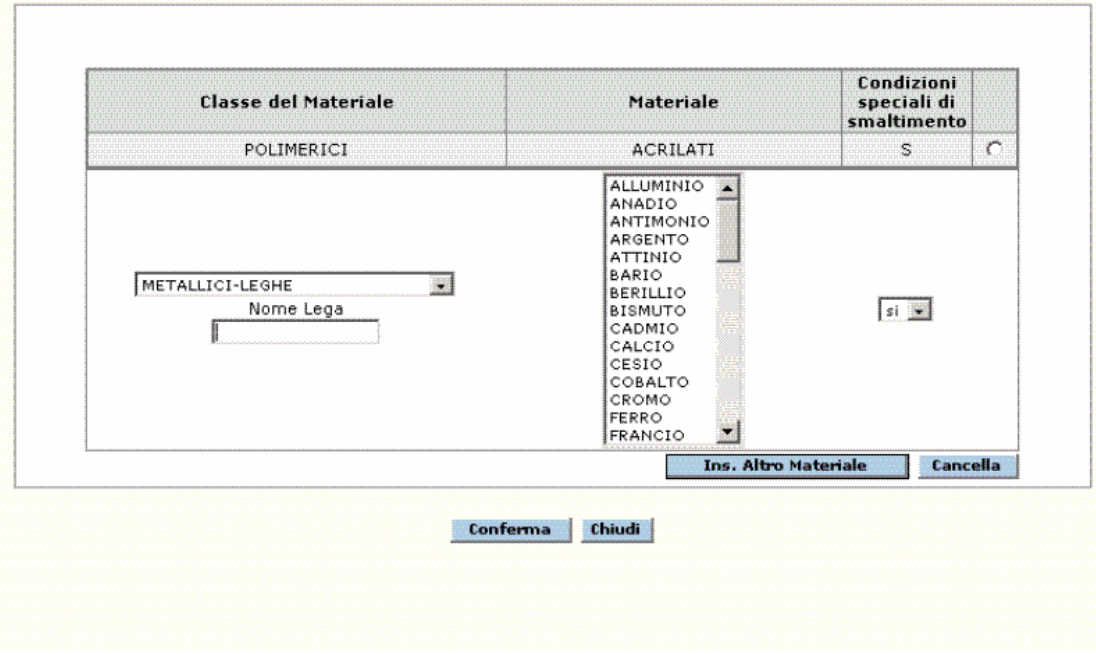
Operations Available

Action	**Description**	**Page Name**
Inserisci Metodo	Confirm the method of sterilisation indicated by the user, providing a new line for the insertion of the new method	Same
Cancella	Eliminates the method of sterilisation selected by the user	Same

Conferma	Closes the window, confirming the actions carried out by the user	Scheda Tecnica

Page Name: LookUPMateriali

This page is displayed in look-up format and permits the insertion and deletion of materials contained in the DM that come into direct contact with the patient. This is the activated by clicking on the "Inserisci/Modifica materali" button, visible on the "Scheda Tecnica" page.
Should the "Classe Materiali" field read "Metallici Leghe" it will the be necessary to indicate the name of the metal.
When saving the data on the specifications data sheet, the user must indicate at least one of the materials contained in the DM that comes in direct contact with the patient.



Materials contained in the DM Detail Fields

Field Name	Description
Class di Materiale	Type of material that the DM is made up of
Materiali	Material that the DM consists of
Condizioni speciali di smaltimento	Indication if the material indicated requires specific disposal
Nome Lega	Name of the metal. This field is displayed if in the corresponding "Classe del Materiale" field the "Metallici-Leghe" option was selected

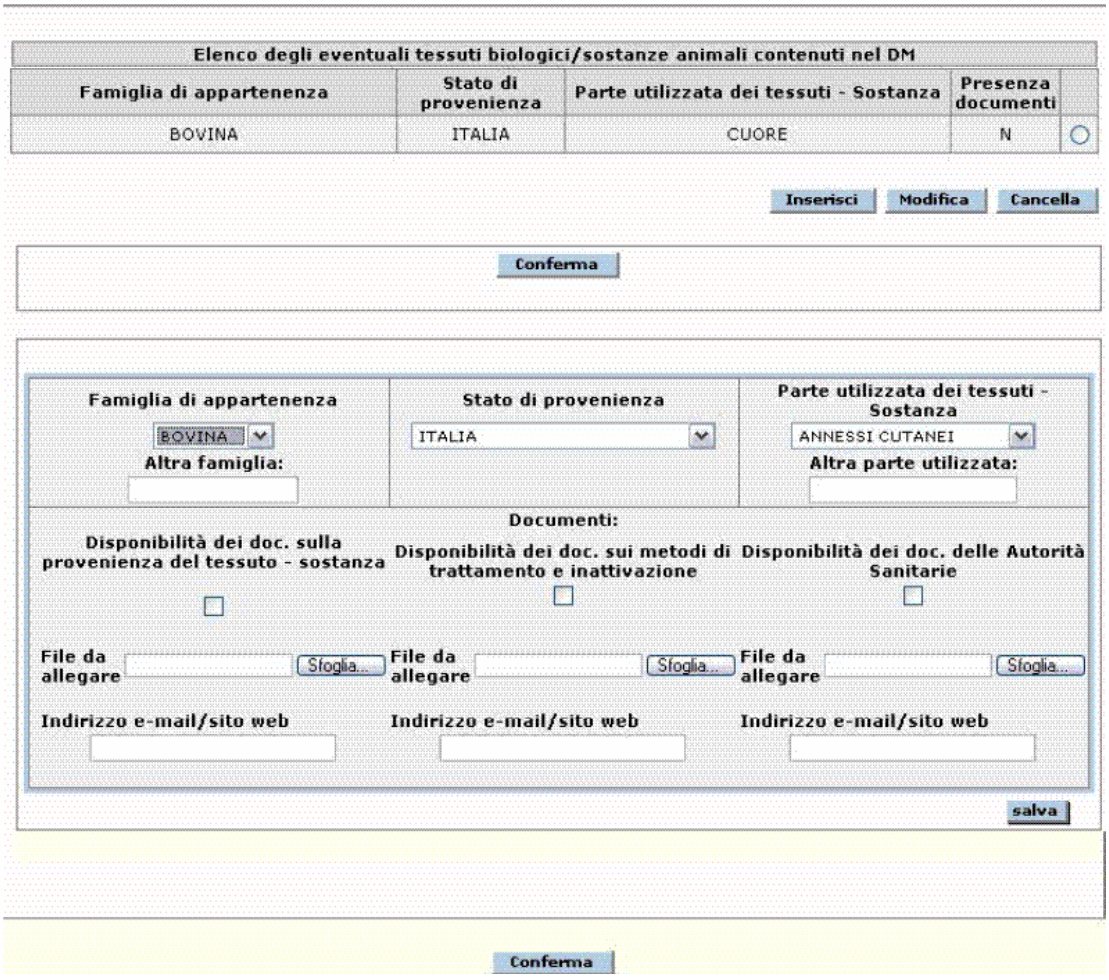
Operations available

Action	Description	Page Name
Ins. Altro Materiale	Confirms the material indicated by the user, providing a new line in order to chose a new	Same

	material	
Cancella	Eliminates the material selected by the user	Same
Conferma	Closes the window, confirming the operations carried out by the user	Scheda Tecnica
Chiudi	Closes the window, with out confirming the actions carried out by the user	Scheda Tecnica

Page Name:LookUpTessuti

This page is displayed in look-up format and allows the user to insert, edit and delete the biological tissues/animal substances contained in the DM.
This is the activated by clicking on the “Inserisci/Modifica materali” button, visible on the “Scheda Tecnica” page.
On the upper part of the page, the list of Biological tissues/animal substances associated with the DM are displayed.
On the lower part of the page, a box is displayed where the user can insert/edit the information related to a biological tissue/animal substance to be associated with the DM.



Tissue data Fields

Field Name	**Description**
Famiglia di appartenenza	Family of origin of the biological tissue/animal substance contained in the DM
Altra Famiglia	Description of the family of origin of the biological tissue/animal substance contained in the DM, if it has not previously been loaded onto the list. This field is required if the corresponding "Famiglia di Appartenenza" was indicated as "Altro", otherwise it is not taken into account
Stato di provenienza	Original condition of the biological tissue/animal substance
Parte utilizzata dei tessuti	Parts of tissue used in DM
Altra parte utilizzata	Description of the parts of the biological tissue/animal substance used in the DM if they haven't been previously loaded onto the list. This field is required if the corresponding "parte utilizzata dei tessuti" was marked "Altro", otherwise it is not taken into account
Disponibilità dei doc. sulla provenienza del tessuto – sostanza	Indication of the presence of documentation on the origin of the tissue – substance
Fila da allegare (in riferimento al campo "Disponibiltà de doc. Sulla provenienza del tessuto – sostanza")	File containing the documentation on the origin of the tissue – substance. The file must be in pdf format. This field is required if the "Disponibiltà de doc. Sulla provenienza del tessuto – sostanza" field has been ticket This field is an alternative to the "Indirizzo email/sito web"
Indirizzo e-mail /sito web (in riferimento al campo "Disponibiltà dei doc. Sulla provenienza del tessuto – sostanza")	Email address/Web site from which the origin of the tissue – substance can be traced. This field is required if the "Disponibiltà dei doc. sulla provenienza del tessuto – sostanza" field was ticket. This field is an alternative to the "File da allegare" field.
Disponibilità dei doc. sui metodi di trattamento e inattivazione	Indication of the presence of documentation on methods of treatment and deactivation
Fila da allegare (in riferimento al campo "Disponibiltà dei doc. sui metodi di trattamento e inattivazione")	File containing the documentation on methods of treatment and deactivation. The file must be in pdf format. This field is required if the "Disponibiltà dei doc. sui metodi di trattamento e inattivazione" field was ticked. This field is an alternative to the "Indirizzo email/sito web" field.
Indirizzo e-mail/sito web (in riferimento al campo "Disponibilità dei doc. sui metodi di trattamento e	Email address/web site where the documentation on methods of treatment and deactivation can be found. This field is required if the "Disponibiltà dei doc. sui metodi di trattamento e inattivazione" field was ticked. This field is

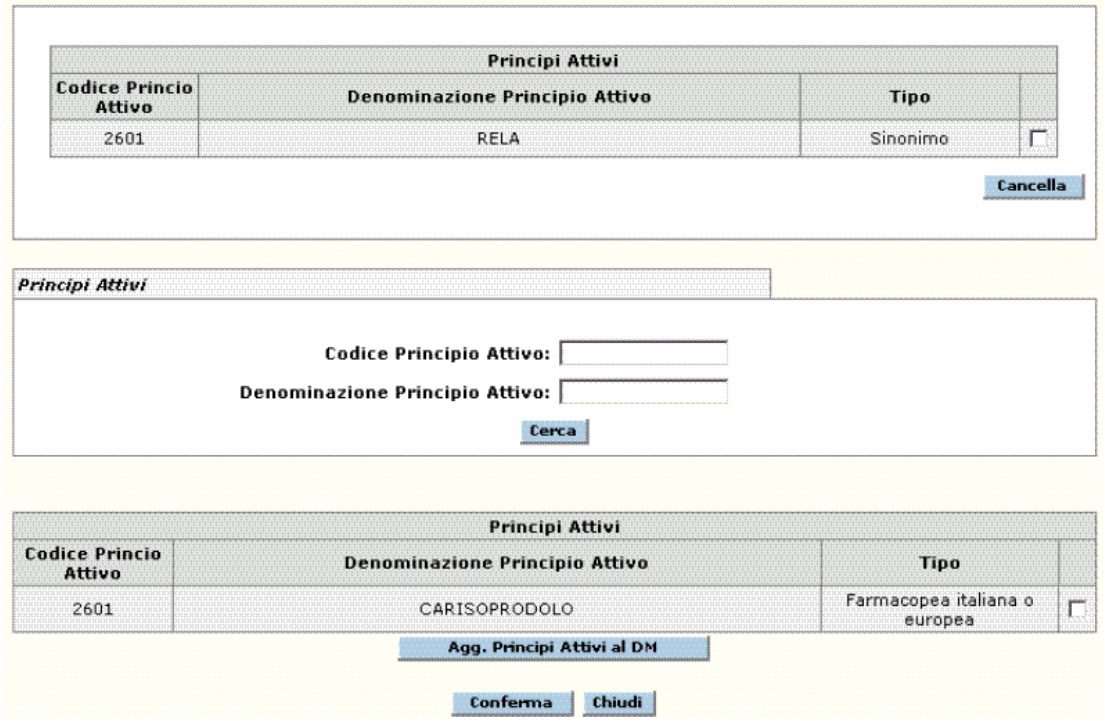
inattivazione”	an alternative to the “File da allegare” field.
Disponibilità dei doc. delle Autorità Sanitarie	Indicate the presence of documentation provided by the Health authority regarding the tissues/substances selected.
Fila da allegare (in riferimento al campo “Disponibilità dei doc. delle Autorità Sanitarie”)	File containing the documentation provided by the Health authority regarding the tissues/substances selected The file must be in pdf form. This field is required if the “Disponibiltà dei doc. delle Autorità Sanitarie” field is ticked. This field is an alternative to the “Indirizzio Email/sito web” field.
Indirizzo Email/sito web (in riferimento al campo “Disponibilità dei doc. delle Autorità Sanitarie”)	Email address/web site where the documentation provided by the health authority regarding the tissue/substance selected can be found. This field is required if the “Disponibiltà dei doc. delle Autorità Sanitarie” field is ticked. This field is an alternative to the “File da allegare” field.

Operations available

Action	**Description**	**Page Name**
Inserisci	Displays a box in which the user can insert information regarding biological tissue/animal substance to be associated with the DM	Same
Modifica	Displays a box in which the user can edit information regarding biological tissue/animal substance selected	Same
Cancella	Eliminates the selected biological tissue/animal substance, associated with the DM	Same
Salva	Saves the information inserted by the user of a biological tissue/animal substance, associated with the DM in the insert/edit box	Same
Conferma	Closes the window, confirming the operations carried out by the user	Scheda Tecnica
Chiudi	Closes the window, without confirming the actions carried out by the user	Scheda Tecnica

Page Name: LookUpSostanze

This page is displayed in look-up format and allows one or more active ingredients to be linked to a DM. This is achieved by clicking the “Inserisci/Modifica principi attivi” button which is found on the “Scheda Tecnica” page.
In the box at the top of the page a list of possible active ingredients associated with the DM is displayed.
In the box in the middle of the page displays the search fields to be determined, (at least one margin must be put in place) in order to obtain the list of active ingredients from which the user may select and then link to the DM.
In the box at the end of the page, a list of consistent active ingredients are visible with the search criteria in place.



Active Ingredients Search Detail Fields

Field Name	**Description**
Codice Principio Attivo	Option to search by inserting the active ingredient code
Nome Principio Attivo	Option to search by inserting the active ingredient name (or part there of)

Active Ingredients List Detail Field

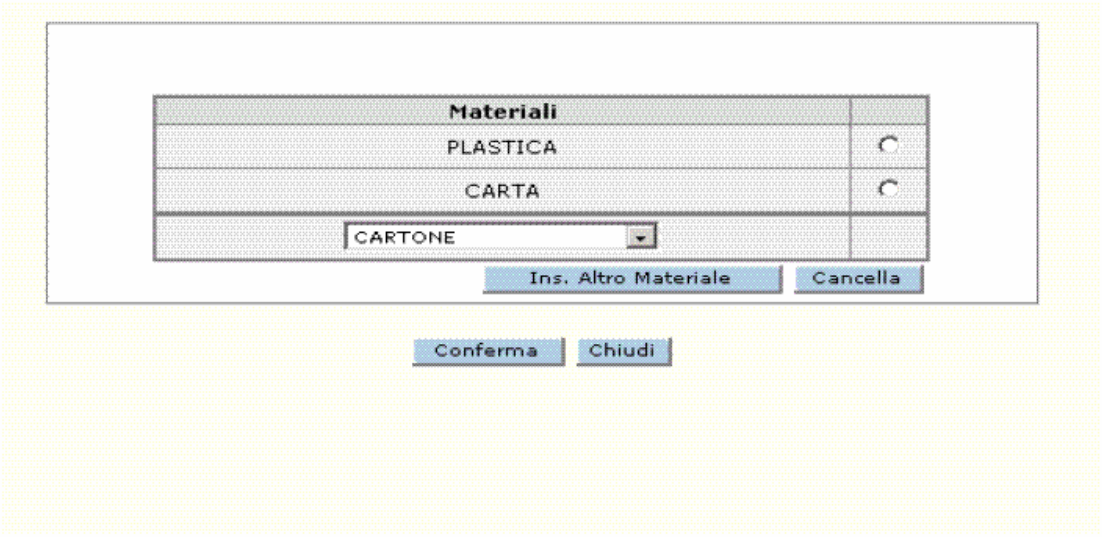
Field Name	**Description**
Codice Principio Attivo	Code of the Active ingredient
Nome Principio Attivo	Name of the Active ingredient
Tipo	Type of Active ingredient

Operations available

Action	**Description**	**Page Name**
Ricerca	Runs a search of the active ingredients base on the search criteria specified	Same
Agg. Principi Attivi al DM	Allows the user to link active ingredients selected to the DM	Same
Cancella	Allows the user to delete the link between the active ingredients selected and the DM	Same
Conferma	Closes the window, confirming the operations carried out by the user	SchedaTecnicaGen
Chiudi	Closes the window, without confirming the actions carried out by the user	SchedaTecnica

Page Name: LookUpMaterialiConfezionamento

This page is displayed in look-up format and allows the insertion and deletion of the primary material used to package the DM. This is activated by clicking the "inserisci/modifica materiali" button found on the "Scheda Tecnica" page.
Only the primary packaging material of sterile DM need be inserted. The material of non sterile DM, does not need to be specified.



Primary packaging material of a DM Detail Fields

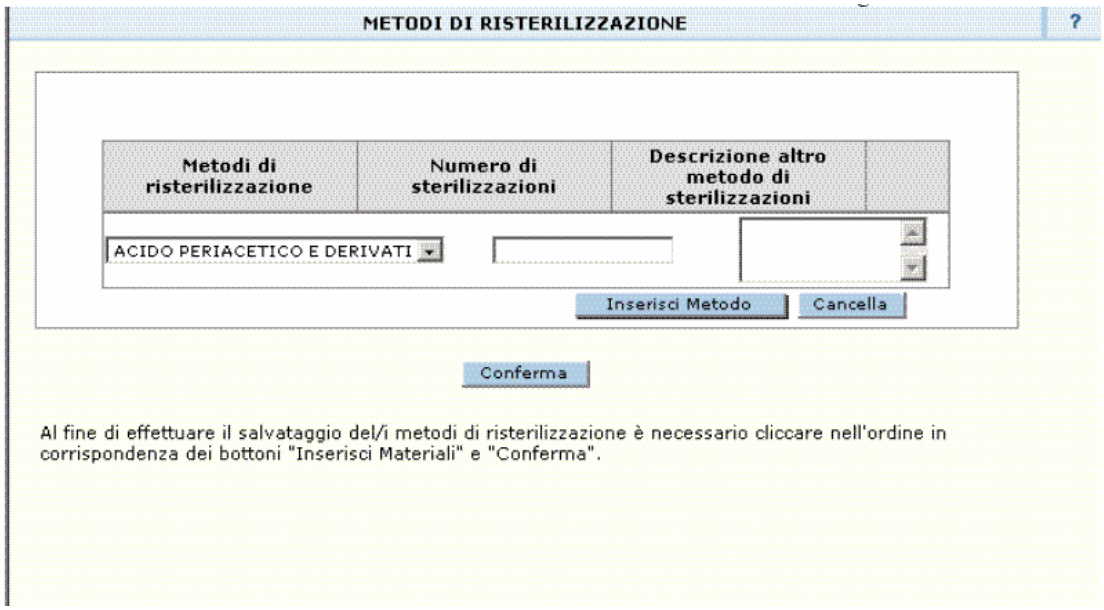
Field Name	Description
Materiali	Material necessary for the primary packaging of the DM

Operations available

Action	Description	Page Name
Ins. Altro Materiale	Confirms the material indicated by the user, providing a new line so that new material can be selected	Same
Cancella	Deletes the material selected by the user	Same
Conferma	Closes the window, confirming the operations carried out by the user	SchedaTecnica
Chiudi	Closes the window, without confirming the actions carried out by the user	SchedaTecnica

Page Name: LookUpMetodiRisteril

This page is displayed in look-up format and allows the user to insert and delete methods of sterilisation applied to the DM which come in direct contact with the patient. It is activated by clicking the “inserisci/modifica materiali” button found on the “Scheda Tecnica” page.
When saving the specification data, at least one method of sterilisation of the DM must be indicated if the DM has been marked as being Sterile



Methods of re-sterilisation of DM Detail Fields

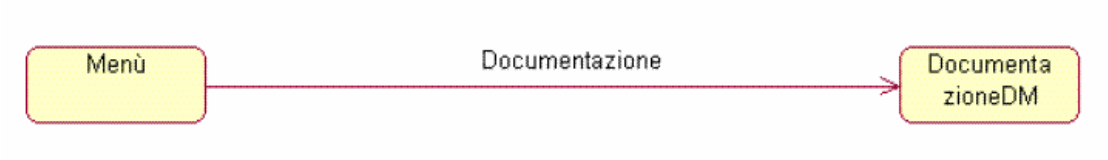
Field Name	Description

Metodo di risterilizzazione	Method used to re-sterilise the DM. This field is required if the "Monouso" field is marked "Si"
Modalità di pulizia/disinfezione	Method used to clean/disinfect the DM. This field is required if the corresponding "Monouso" field was marked "No"
Se altro metodo di sterilizzazione, specificare	Description of method of re-sterilisation if it is not found on the list previously loaded.
Numero di sterilizzazioni	Maximum number of times it is permitted to sterilise a DM.. To specify that an illimited number of sterilisations are allowed the option 'Illimitato' must by selected. Otherwise the corresponding field must be filled in with the number of sterilisations allowed. The field is editable if the check "Illimitato" its not selected. This field is required if in the "Monouso" field has been set to "No"

Operations available

Action	Description	Page Name
Inserisci Metodo	Confirms the method of re-sterilisation indicated by the user, providing a new line so that new method can be inserted	Same
Cancella	Deletes the method of re-sterilisation selected by the user	Same
Conferma	Closes the window, confirming the actions carried out by the user	SchedaTecnica

2.3.1.8.1.3 Documentation



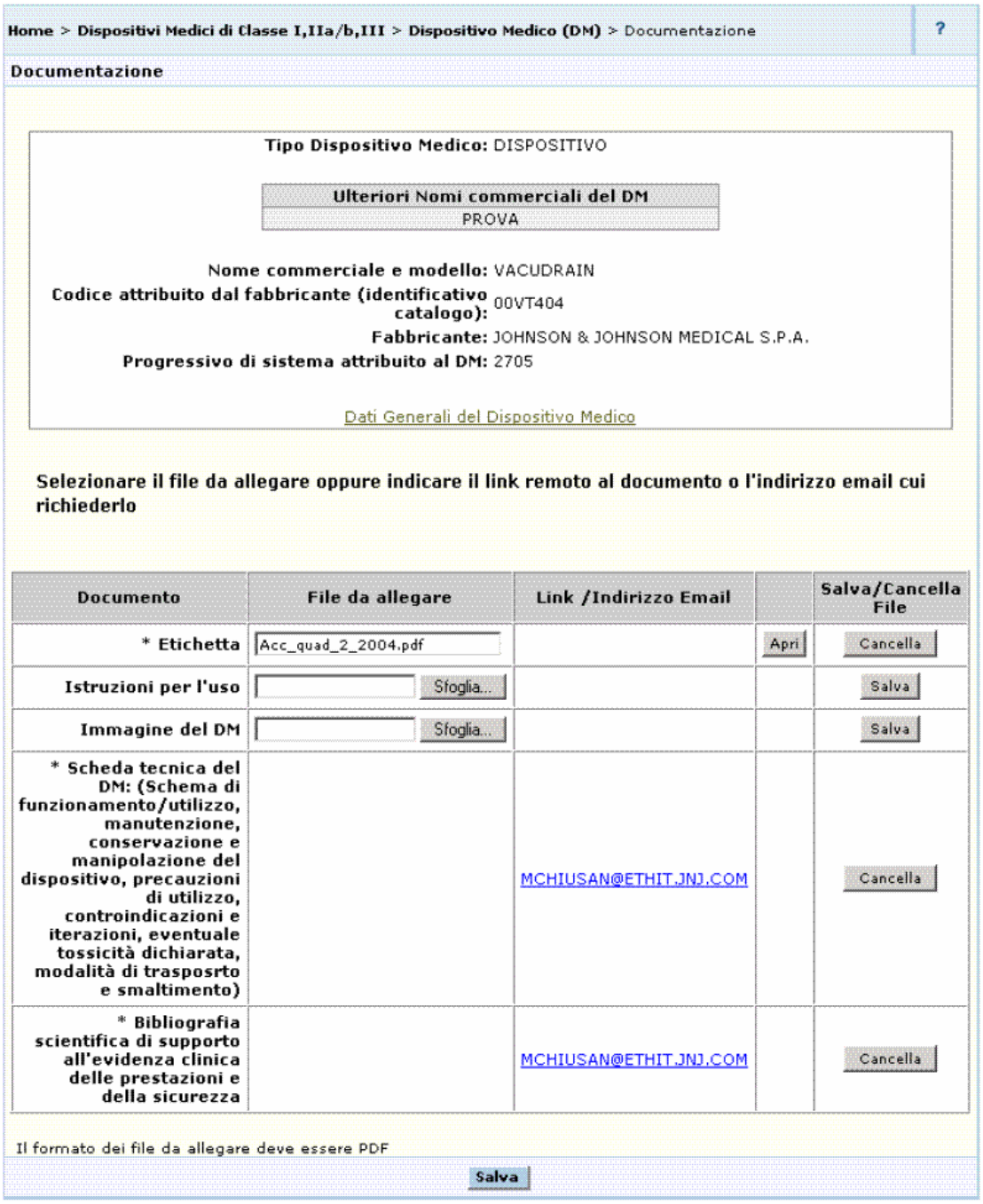
This page allows the user to insert documentation attached to a DM. This page is not accessible in the following phases:

- During the insertion phase of the DM after the registration of the general data
- During the editing phase of the DM
- During the insertion phase of the DM by means of coping one that already exists in the system

In the upper section of the page, the principle data of the DM are displayed as well as the “Dati Generali del Dipositivo Medico” link which opens the page containing the general data of the DM.

All of the fields on this page are required in order for the FAB/MAN/RIC/ASD to validate the DM.

Page Name: DocumentazioneDM



Documentation Detail Fields

Field Name	Description

Etichetta	File containing the label of the DM. Required
	The attached file must be a pdf file
Istruzioni per l'uso	File containing the direction for use of the DM
Imagine del DM	File containing the image of the DM. Not obligatory. The file attached must be a pdf file
Scheda tecnica del DM: (Schema di funzionamento/utilizzo, manutenzione, conservazione e manipolazione del dispositivo, precauzioni di utilizzo, controindicazioni e iterazioni, tossicità dichiarata, modalità di trasporto e smaltimento)	The file containing the specifications of the DM or alternatively the link to the site where the same information may be found. Required. The file attached must be in pdf format.
Bibliografia scientifica di supporto all'evidenza clinica delle prestazioni e della sicurezza	File containing the Scientific bibliography, supporting the clinical evidence of the effectivness and safety of the DM or alternatively a link to a site where the same information may be found. Required. The file attached must be in pdf format

Operations available

Action	**Description**	**Page Name**
Salva	Allows a file uploaded or a link entered, to be saved	Same
Cancella	Allows user to delete a file or link	Same
Apri	Allows the user to download he attached document	

2.3.1.8.1.4 Commercial Data

Page Name: DatiCommercialiDM

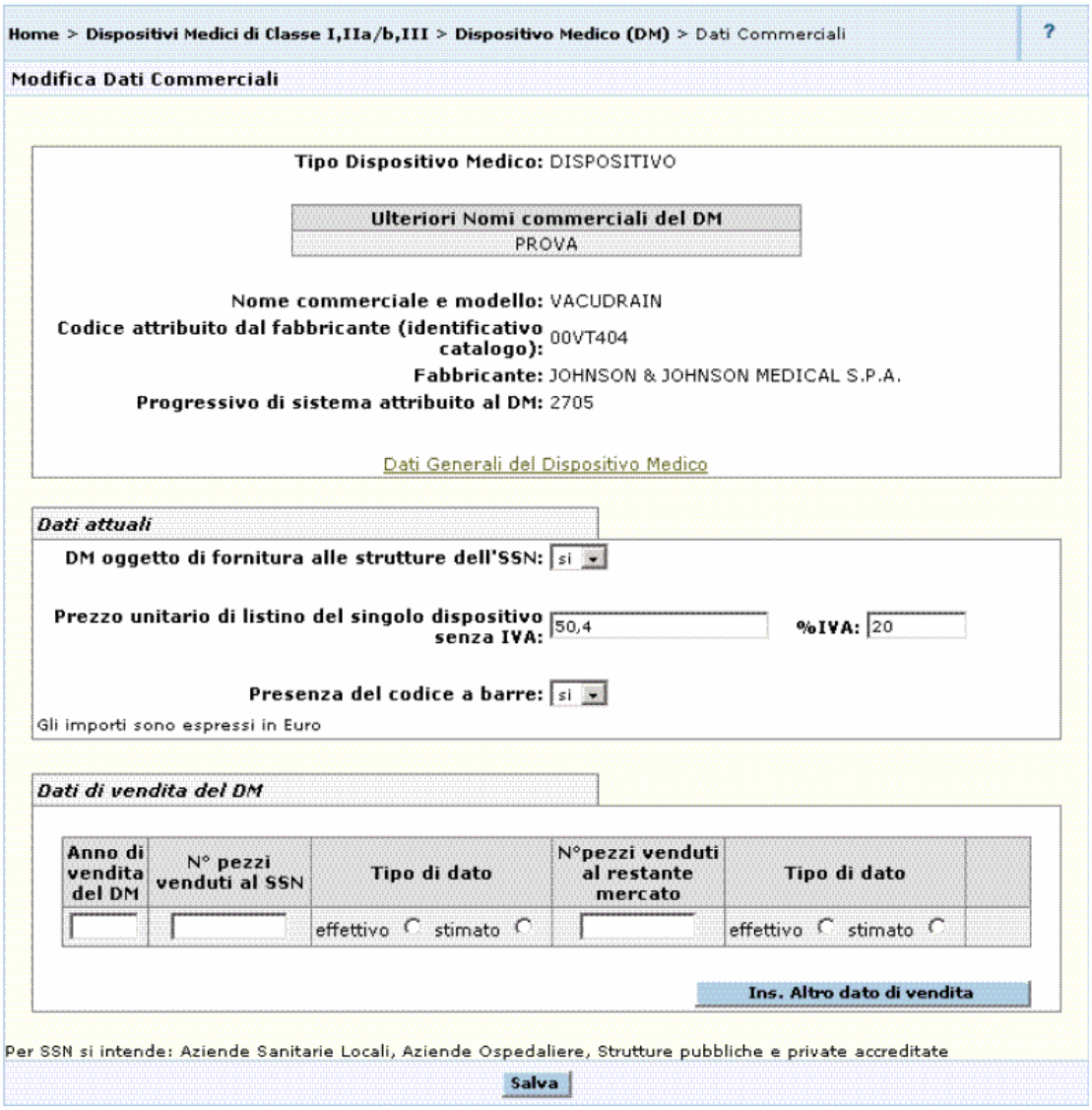
This page allows the user to insert/edit the commercial data of a DM. The commercial data of a DM are subdivided in two areas.

- Current data of the DM
- Annual sales details of the DM

The insertion page of commercial data of a DM is accessible by the user in the following cases:

- During the insertion phase of the DM after the registration of the general data
- During the editing phase of the DM
- During the insertion phase of the DM by means of coping one that already exists in the system

In the upper section of the page, the principle data of the DM are displayed as well as the “Dati Generali del Dipositivo Medico” link which opens the page containing the general data of the DM.



Commercial data Fields

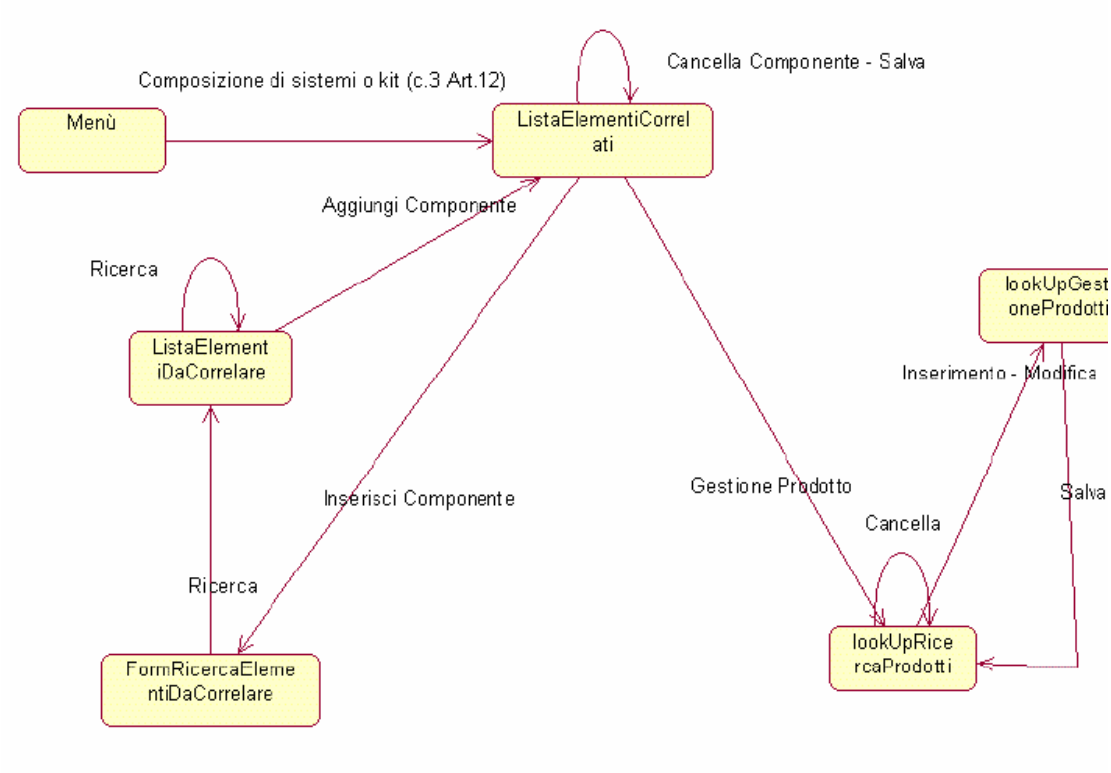
Field Name	Description
Current data	
DM oggetto di fornitura alle strutture dell'SSN	Indication whether or not the DM is destined to be used by the SSN
Prezzo unitario di listino del singolo dispositivo senza	Unit sale price of a DM free of tax

IVA	
%IVA	Indication of the IVA applied to the DM
Presenza del codice a barre	Indication as to whether or not the DM bears a barcode
DM Sales data	
Anno di vendita DM	Indication of the year DM was sold
No. pezzi venduti al SNN	Indication of the number of pieces sold to the National Health Service. This field is required if the year of sale has been entered.
Tipo di dato	Indication of the type of data (No. of pieces sold to the SSN) either estimated or exact
No. pezzi venduti al restante mercato	Indication of the number of DM pieces old (excluding pieces sold to the SSN). This field is required if the year of sale has been entered
Tipo di dato	Indication of the type of data (No. of pieces sold to the rest of the market) either estimated or exact This field is required if the year of sale has been entered

Operations available

Action	**Description**	**Page Name**
Ins. Altro dato di vendita	Adds an empty line in which the user can insert the commercial information of a DM regarding a sales year	Same
Salva	Allows the information entered to be saved	Same

2.3.1.8.1.5 Composition of Systems and kits (Para.3 Art.12)



Page Name: ListaElementiCorrelati

This page allows the user to add or delete a component in a system or kit in accordance with Para.3 Art.12. The components of a system or kit in accordance with Para.3 Art12. There are three possible types:

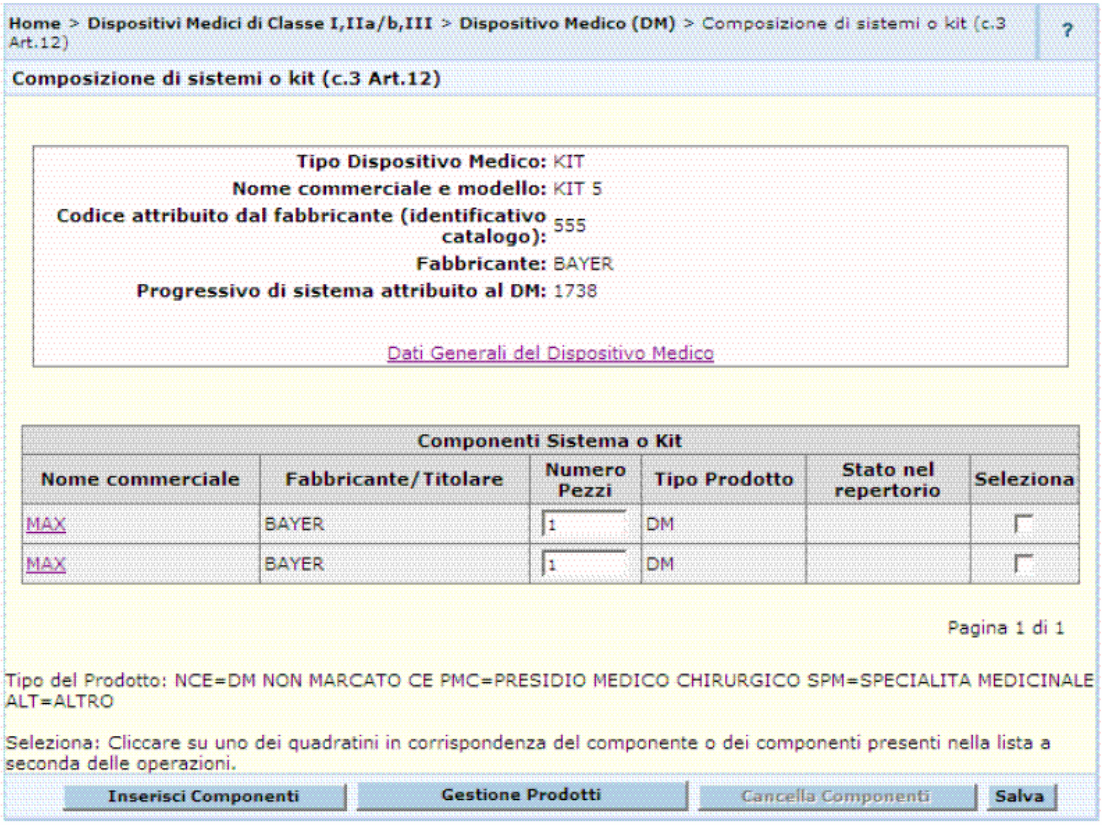
- CE marked DM
- Non-CE marked DM
- Non-DM articles

This page is accessible by the user in the following cases:

- During the insertion phase of a System or kit after the registration of the general data
- During the editing phase of a System or kit
- During the insertion phase of a System or kit by means of coping one that already exists in the system

In the upper section of the page, the principle data of the DM are displayed as well as the “Dati Generali del Dipositivo Medico” link which opens the page containing the general data of the DM.

Each system or kit's commercial name has a corresponding link which allows the user to see additional detailed information about the component selected.



Component list Data Fields

Field Name	Description
Nome Commerciale	Commercial name of DM or Non-DM article
Fabbricante/Titolare	Indication of the number of pieces which the system or kit require, regarding the components
Tipo prodotto	The following types of products can be recognised (Para.3 Art.12) as a system or kit: - DM (Medical Device) - NCE (Non-CE marked DM) - PMC (Medical and surgical aids) - SM Medicines - ALT (Other Non-DM type of Article)
Stato nella base dati	The status of the DM in the database. The status can change in the following order: • L: Processing • V: Valid • P: Published

Operations available

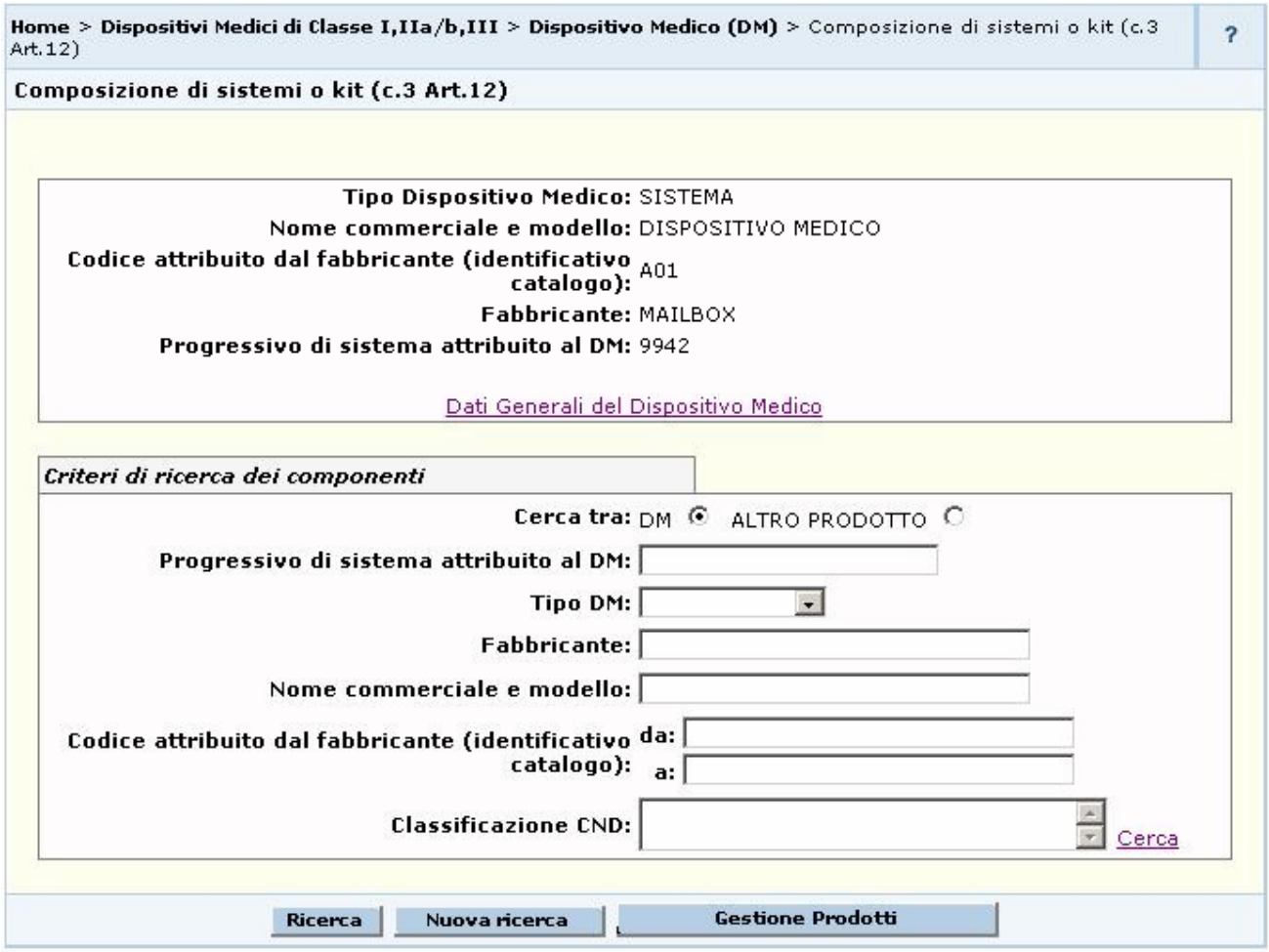
Action	Description	Page Name
Inserisci Componente	Grants the user access to the component search page in order to make additions to a system or kit	FormRicercaElementiDa Correlare
Gestione Prodotti	Opens a window where the user has the option to manage Non-DM articles i.e. the "Altro" and Non-CE marked kind	LookUpRicercaProdotti.
Cancella Componenti	Allows the user to delete components selected from the composition of the system or kit	Same
Salva	Allows the information entered to be saved	Same

Page Name: FormRicercaElementiDaCorrelare (DM)

This page allows the user to put search criteria in place in order to view the DM list or the list of other Non-DM products to add as components to the system or kit. Depending on the criteria specified in the "Cerca tra" field, the page will display different search criteria. In this paragraph we will examine the case in which the user intends to search among DM.

After having requested a DM list, it is necessary to put another search margin in place.

In the upper section of the page, the principle data of the DM are displayed as well as the "Dati Generali del Dipositivo Medico" link which opens the page containing the general data of the DM.



DM Component Search Fields

Field Name	Description
Cerca Tra	The user must provisionally choose if he intends to request a DM list or other Non-DM product list. Different search criteria will be displayed depending on this choice
Progressivo di sistema attribuito al DM	Option to serch a Medical Device by its identification number assigned during registration into the database.
Tipo DM	Indicate the class of Medical device. There are the following types of DM: • Device • System • Kit
Fabbricante	The user can insert the name (or part there of) of the Manufacturer of the DM
Codice attribuito dal fabbricante (identicativo catalogo) da/a	Option to indicate the range of codes which includes the product code assigned to the DM by the Manufacturer.
Nome commerciale e modello	The DM's name (or beginning of) given by the manufacturer, can be inserted
Classificazione CND	Indicates the national classification of the DM This field is cannot be edited. TO select a CND

	classification, click on the “cerca” link; a look-up will open from which it will be possible to search for a CND classification by code and description

Operations available

Action	Description	Page name
Gestione Prodotti	Opens a window where the user has the option to manage Non-DM articles i.e. the “Altro” and Non-CE marked kind	LookUpRicercaProdotti.
Ricerca	Runs a search with criteria put in place and displays the DM list or list of Non-DM products that match the same criteria	ListaElementiDaCorrelare
Reset	Clears the search criteria previously put in place	Same

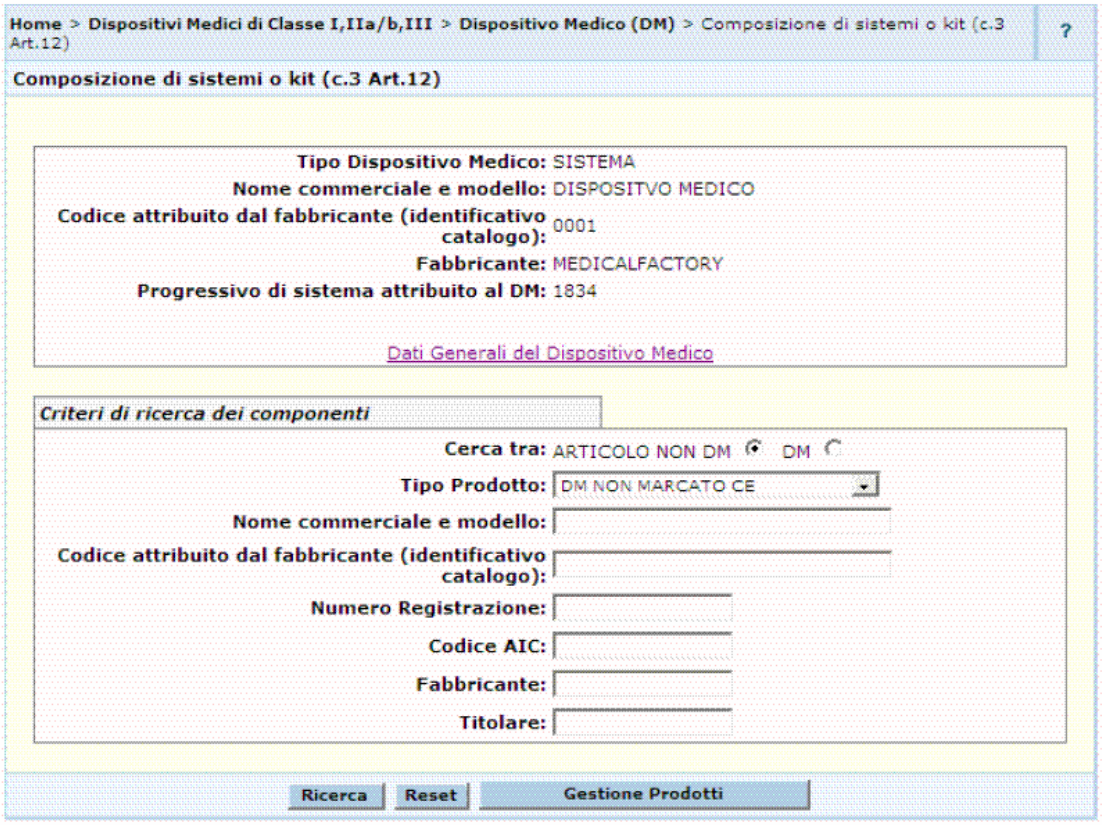
Page Name: FormRicercaElementiDaCorrelare (Articoli Non-DM)

This page allows the user to put search criteria in place in order to view the listo f DM and other Non-DM products to add as components of a system or kit. This page will display different search criteria, depending on the type of DM chosen. In the is paragraph we will examine the case in which the user wishes to search among the Non-DM items.
In particular, if the user chooses “Articolo Non-DM” he can refine his search choosing between

- Non -CE marked DM
- Medicinies
- Medical and surgical aids
- Other

Should a “DM non marcati CE” be chosen, a search will be run of the Non -CE marked DM registered in the database, should “Specialità Medicinali” be chosen, a search will be run in the General Pharmaceutical Database, Should “Presidi Medici Chirurgici” be chosen, a search will be run in the database of the P.M.C registered, should a “Altro” be chosen, a search will be run of the “Altro” type Non-DM articles registered in the database.

In the upper section of the page, the principle data of the DM are displayed as well as the “Dati Generali del Dipositivo Medico” link which opens the page containing the general data of the DM.



Non-DM article components Search Detail Fields

Field Name	Description
Cerca Tra	The user must provisionally choose if he intends to request a DM list or other non -DM product list. Different search criteria will be displayed depending on this choice
Tipo prodotto	The user can choose between the following types of product: • Non -CE marked DM • Surgical and Medical Aids • Medicines • Other
Nome commerciale e modello	The DM's name (or beginning of) given by the manufacturer, can be inserted
Fabbricante	The user can insert the name (or part there of) of the Manufacturer of the DM
Codice attribuito dal fabbricante (identicativo catalogo)	The code attributed to the DM by the manufacturing company can be indicated (referring to Non-CE marked DM and to others)
Numero registrazione	The registration number refers

	exclusively to surgical and medical aids
Codice AIC	The AIC code refers exclusively to Medicinal products
Fabbricante	The name of the Manufacturer (or part thereof) can be indicated (referring to non -stamped DM, Surgical and medical aids and other)

Operations available

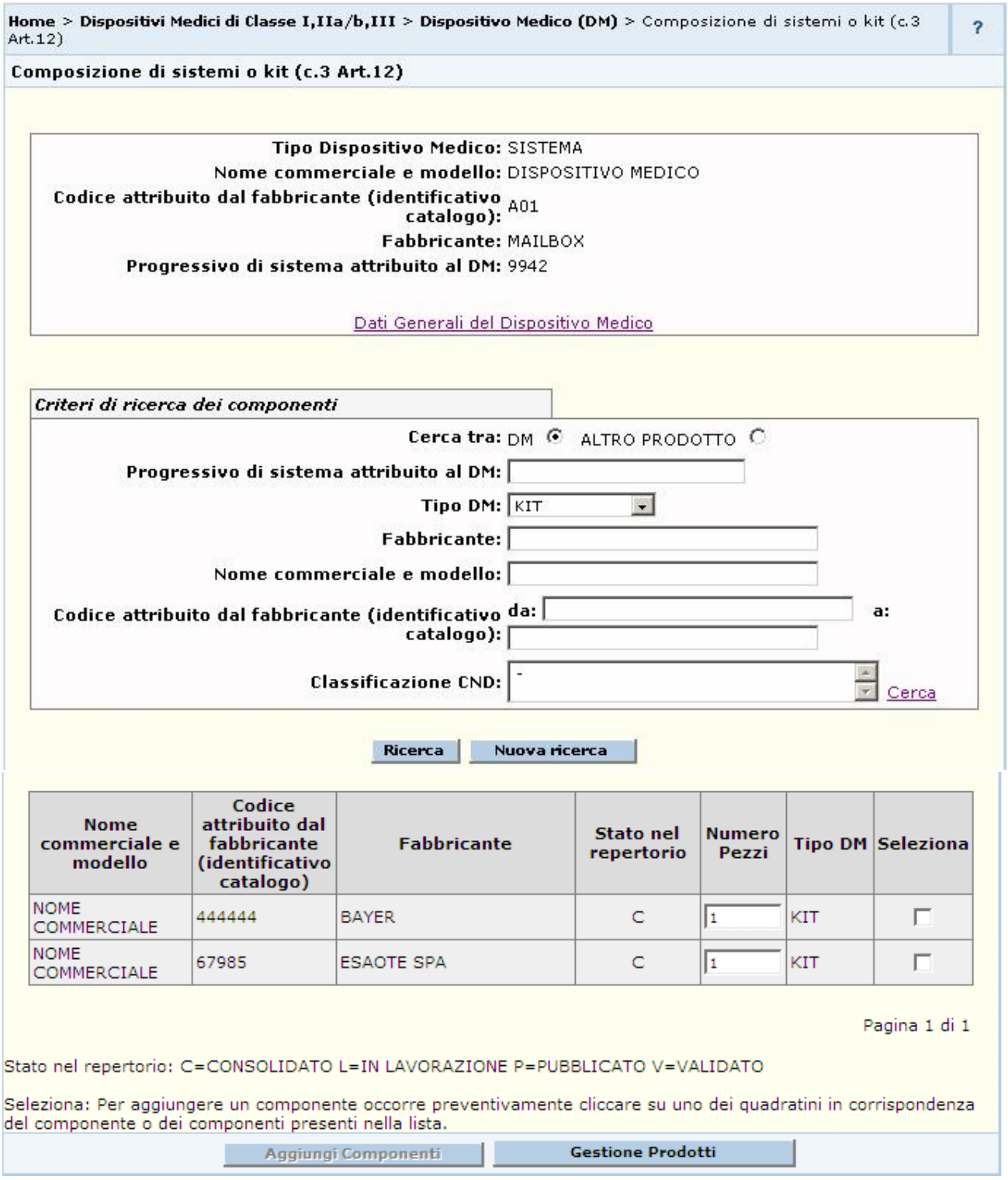
Action	**Description**	**Page name**
Gestione Prodotti	Opens a window where the user has the option to manage Non-DM articles i.e. the "Altro" and Non-CE marked kind	LookUpRicercaProdotti.
Ricerca	Runs a search with criteria put in place and displays the DM list or list of non- DM products that match the same criteria	ListaElementiDaCorrelare
Reset	Clears the search criteria previously put in place	Same

Page Name: ListaElementiDaCorrelare

This page allows the user to :

- View the list of DM and then choose which components to add to the system or kit
- Run a new search

In the upper section of the page, the principle data of the DM are displayed as well as the "Dati Generali del Dipositivo Medico" link which opens the page containing the general data of the DM.



DM Components Search Detail Fields

Field Name	Description
Cerca tra	The user must provisionally choose if he intends to request a DM list or other Non-DM product list. Different search criteria will be displayed depending on this choice
Progressivo di sistema	Option to serch a Medical Device by its identification

attribuito al DM	number assigned during registration into the database.
Tipo DM	Indicate the class of Medical device. There are the following types of DM: • Device • System • Kit
Fabbricante	The user can insert the name (or part thereof) of the Manufacturer of the DM
Codice attribuito dal fabbricante (identicativo catalogo) da/a	Option to indicate the range of codes which includes the product code assigned to the DM by the Manufacturer.
Nome commerciale e modello	The DM's name (or beginning of) given by the manufacturer, can be inserted
Classificazione CND	Indicates the national classification of the DM This field is cannot be edited. To select a CND classification, click on the "cerca" link; a loo-up will open from which it will be possible to search for a CND classification by code and description
Numero Pezzi	Indication of the number of pieces the system or lit requires, referring to the components

DM List Detail Fields

Field Name	**Description**
Nome commerciale e modello	The DM's name given by the manufacturer
Codice attribuito dal fabbricante (identicativo catalogo)	The code attributed to the DM by the manufacturing company
Fabbricante	The name of the Manufacturer of the DM
Stato nella base dati	
Numero pezzi	Indication of pieces which the system or kit requires (referring to the components). This field can be edited
Tipo DM	Indicate the class of Medical device. There are the following types of DM: • Device • System • Kit

Operations available:

Action	**Description**	**Page name**
Ricerca	Runs a search with criteria put in place and displays the DM list or list of Non-DM products that match the same criteria	Same
Reset	Clears the search criteria previously put in place	Same

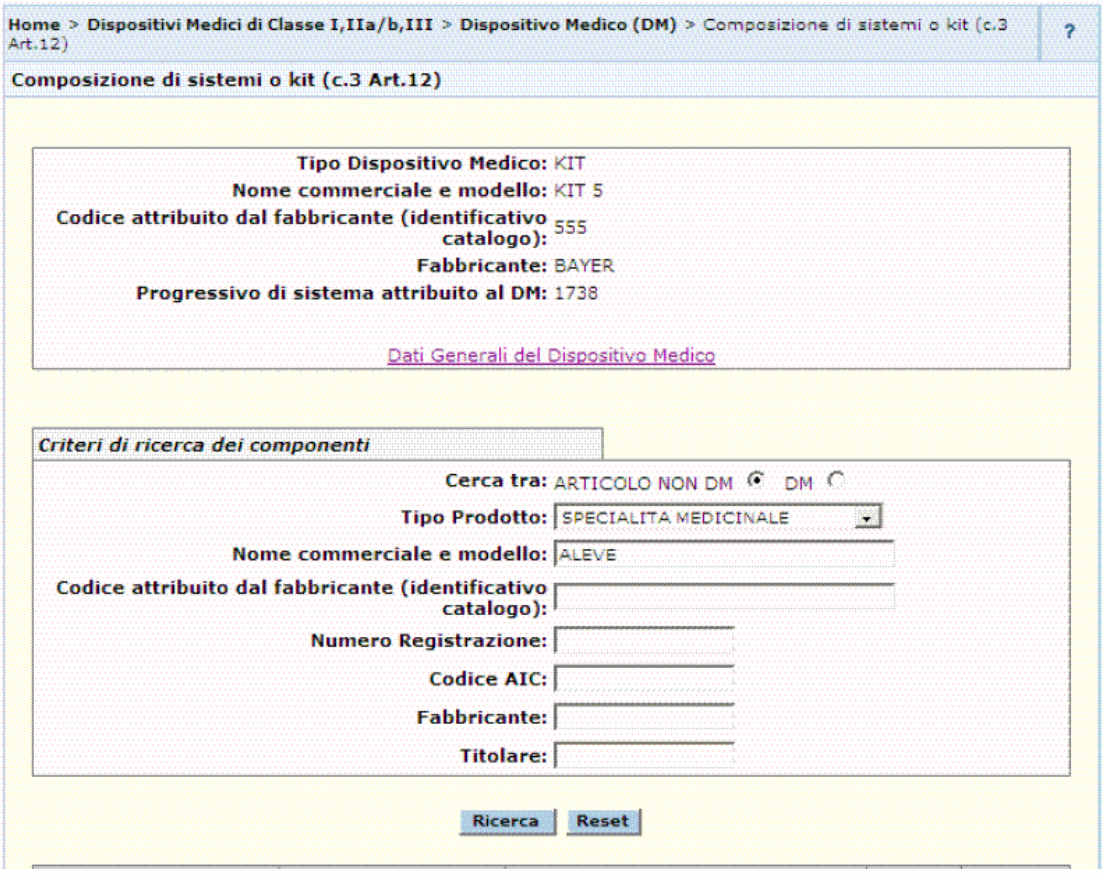
Gestione Prodotti	Opens a window where the user has the option to manage Non-DM articles i.e. the "Altro" and Non-CE marked kind	LookUpRicercaProdotti.
Aggiungi Componente	Adds the component(s) selected, to the system or kit	ListaElementiCorrelati

Page Name: ListaElementiDaCorrelare (Articoli Non-DM)

This page allows the user to :

- View the list of DM and then choose which components to add to the system or kit
- Run a new search

In the upper section of the page, the principle data of the DM are displayed as well as the "Dati Generali del Dipositivo Medico" link which opens the page containing the general data of the DM.



Nome commerciale e modello	Codice AIC	Titolare	Numero Pezzi	Seleziona
ALEVE - "220 MG COMPRESSE RIVESTITE CON FILM"10 COMPRESSE	032790014	ROCHE S.P.A.	1	
ALEVE - "220 MG COMPRESSE RIVESTITE CON FILM"20 COMPRESSE	032790026	ROCHE S.P.A.	1	

Pagina 1 di 1

Stato nel repertorio: C=CONSOLIDATO L=IN LAVORAZIONE P=PUBBLICATO V=VALIDATO

Seleziona: Per aggiungere un componente occorre preventivamente cliccare su uno dei quadratini in corrispondenza del componente o dei componenti presenti nella lista.

Aggiungi Componenti | Gestione Prodotti

Non-DM Item Components Search Detail Fields

Field Name	Description
Cerca Tra	The user must provisionally choose if he intends to request a DM list or other non -DM product list. Different search criteria will be displayed depending on this choice
Tipo prodotto	The user can choose between the following types of product: • Non-CE marked DM • Surgical and Medical Aids • Medicines • Other
Nome commerciale e modello	The DM's name (or beginning thereof) given by the manufacturer, can be inserted
Fabbricante	The user can insert the name (or part thereof) of the Manufacturer of the DM
Codice attribuito dal fabbricante (identicativo catalogo)	The code attributed to the DM by the manufacturing company can be indicated (referring to non- CE marked DM and to others
Numero registrazione	The registration number refers exclusively to surgical and medical aids
Codice AIC	The AIC code refers exclusively to Medicinal products
Fabbricante	The name of the Manufacturer (or part thereof) can be indicated (referring to non stamped DM, Surgical and medical aids and other)
Titolare	The name of the Title holder (or part thereof) can be indicated (referring exclusively to Medicinal products)

Non-DM Item List Detail Fields

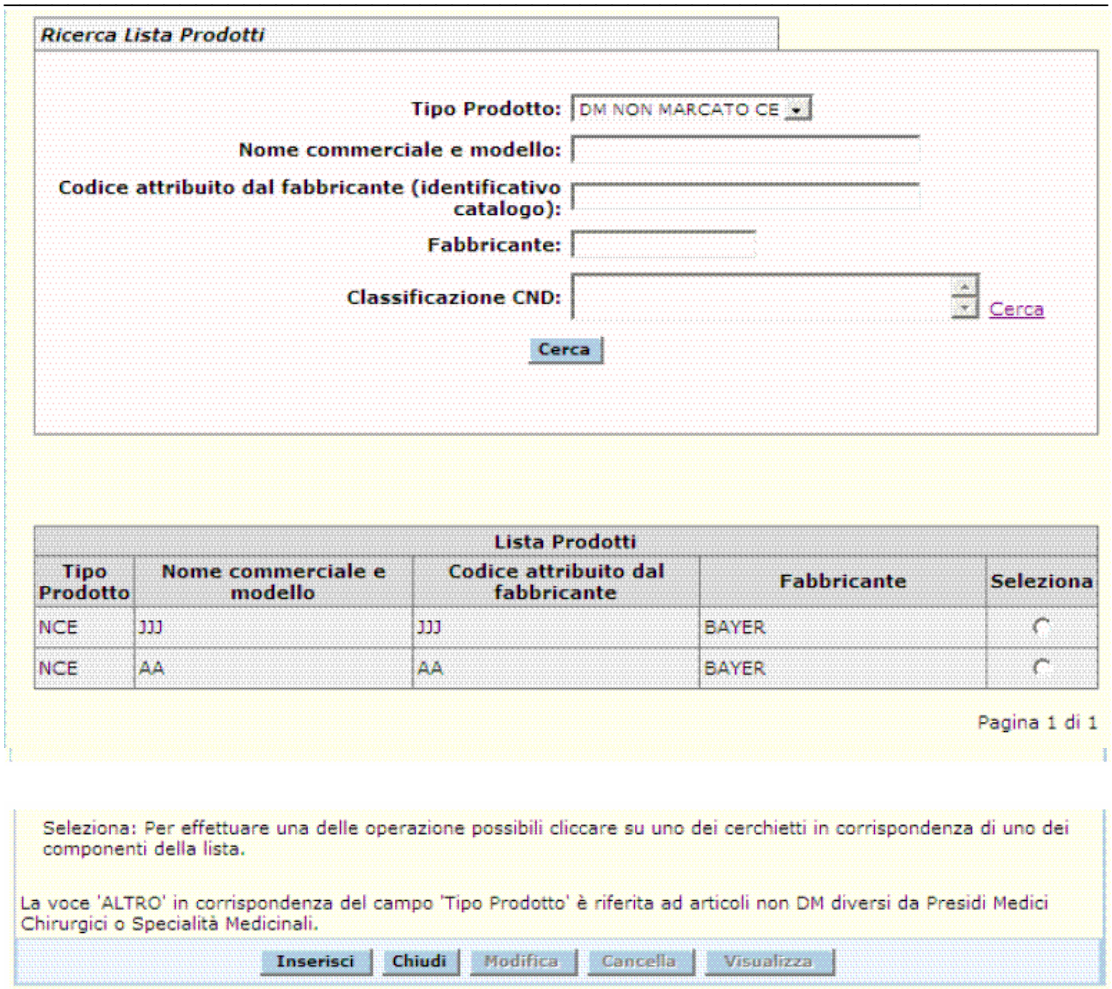
Field Name	Description
Nome commerciale e modello	The name given to the product by the manufacturer
Codice attribuito dal	The code attributed to the product by the manufacturing

fabbricante (identicativo catalogo)	company (refering to non-stamped DM and other)
Numero registrazione	The registration number refers exclusively to surgical and medical aids
Codice AIC	The AIC code refers exclusively to Medicinal products
Fabbricante	The name of the Manufacturer (referring to non stamped DM, Surgical and medical aids and other)
Titolare	The Title holder referring exclusively to Medicinal products)
Numero pezzi	Indication of pieces which the system or kit requires referring to the components. This field can be edited

Operations available:

Action	**Description**	**Page name**
Ricerca	Runs a search with criteria put in place and displays the DM list or list of Non-DM products that match the same criteria	Same
Reset	Clears the search criteria previously put in place	Same
Product management	Opens a window where the user has the option to manage Non-DM articles i.e. the “Altro” and Non -CE marked kind	LookUpRicercaProdotti.
Aggiungi Componente	Adds the component(s) selected, to the system or kit	ListaElementiCorrelati

Page Name: LookUpRicercaProdotti
This page is displayed in look-up format and can be activated in the system and kit components function area (Para.3 Art.12). It allows the user to enter search criteria in order to view the non stamped DM list or other non-DM products; type “altro”.



Product Search Detail Fields

Field Name	**Description**
Tipo prodotto	The user can choose between the following types of product: • Non –CE marked DM • Other
Nome commerciale e modello	The commercial name (or beginning thereof) of the product, can be inserted
Codice attribuito dal fabbricante (identicativo catalogo)	The code attributed to the DM by the manufacturing company can be specified
Fabbricante	The user can specify the name (or part thereof) of the Manufacturer of the product
Classificazione CND	The user can search for the national classification of the

	product (referring solely to non -CE marked DM) This field is cannot be edited. To select a CND classification, click on “cerca”; a look-up will open from which it will be possible to search for a the same classification by code and description (or part there of)

Product List detail Fields

Field Name	**Description**
Tipo prodotto	The user can choose between the following types of product: • Non -CE marked DM (NCE) • Other (ALT)
Nome commerciale e modello	The name given to the product by the manufacturer
Codice attribuito dal fabbricante (identicativo catalogo)	The specific code attributed to the product by the manufacturer
Fabbricante	The name of the Manufacturer of the product

Operations available:

Action	**Description**	**Page name**
Cerca	Runs a search with criteria put in place and displays the DM list or list of Non-DM products that match the same criteria	Same
Chiudi	Closes the product management window	The page from which the window was opened
Inserimento	Displays the insertion page of a product	LookUpGestioneProdotti
Modifica	Displays a details page (in editable mode) of the product selected from the list	LookUpGestioneProdotti.
Visualizza	Displays a detail page (in non editable mode) of the product selected from the list	LookUpGestioneProdotti.
Cancella	Deletes the product selected from the list	Same

Page Name: LookUpGestioneProdotti

This page allows the user to insert/edit/visualise the information regarding the Non-CE marked DM or other non -DM products; type “Altro”.

Detail Fields

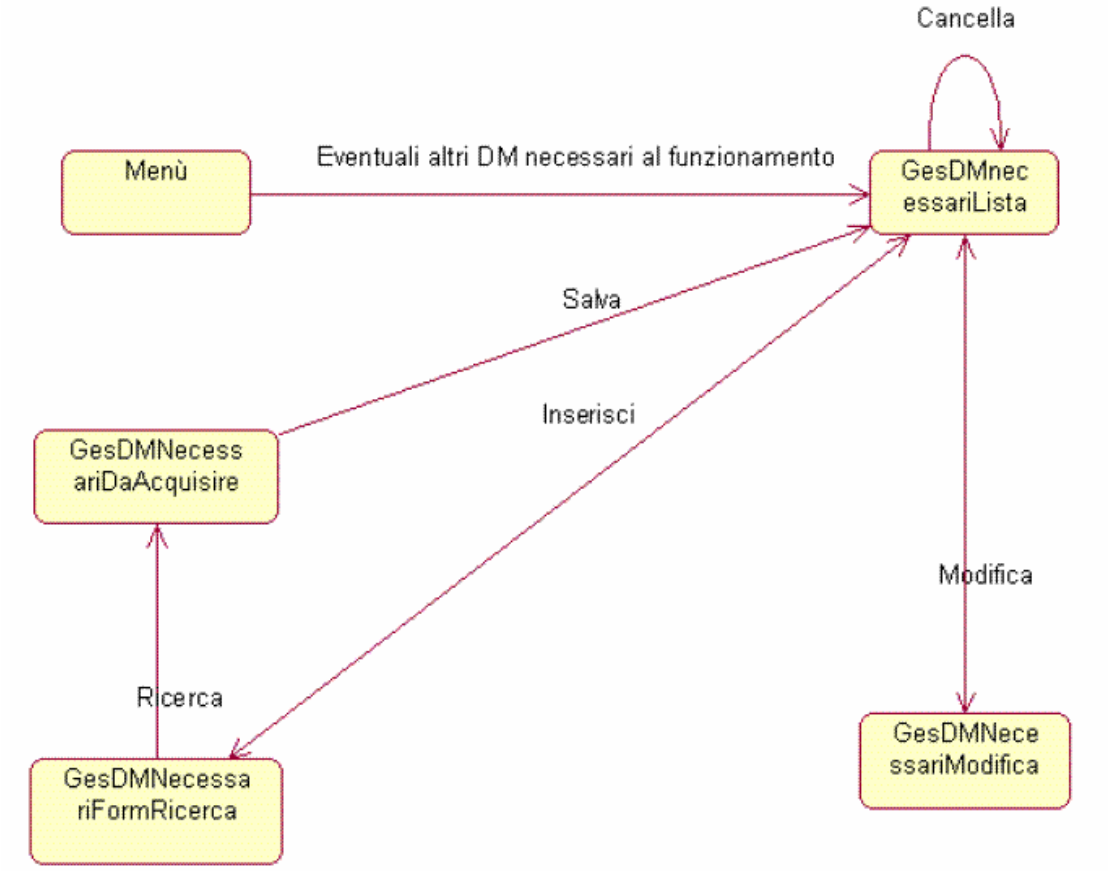
Field Name	Description
Tipo prodotto	The user can choose between the following types of product: • Non-CE marked DM • Other
Nome commerciale e modello	The commercial name of the product as given by the Manufacturer
Codice attribuito dal fabbricante (identicativo catalogo)	The specific code attributed to the DM by the manufacturer
Fabbricante	Indicates the manufacturer of the product. For Non CE marked Medical Devices only this field cannot be edited. In this case it is set by default to the manufacturer name indicated by the user in the “Gestione Dati Azienda” feature. To select a different manufacturer click on “Cerca”; a look-up window will appear from which the user can search for and select a new manufacturer.
Classificazione CND	Indicates the national classification of the DM (referring solely to Non-CE marked DM) This field is cannot be edited. To select a CND classification, click on “cerca”; a look-up will open from which it will be possible to search for a the same classification by code and description (or part thereof)

Operations available:

Action	Description	Page name
Salva	Saves the information entered by the user	Same
Chiudi	Closes the product management window	The page from which the window was opened
Lista	Allows the user to return to the product	LookUpRicercaProdotti.

Prodotti	search page	

2.3.1.8.1.6 Other possible DM required for one to function



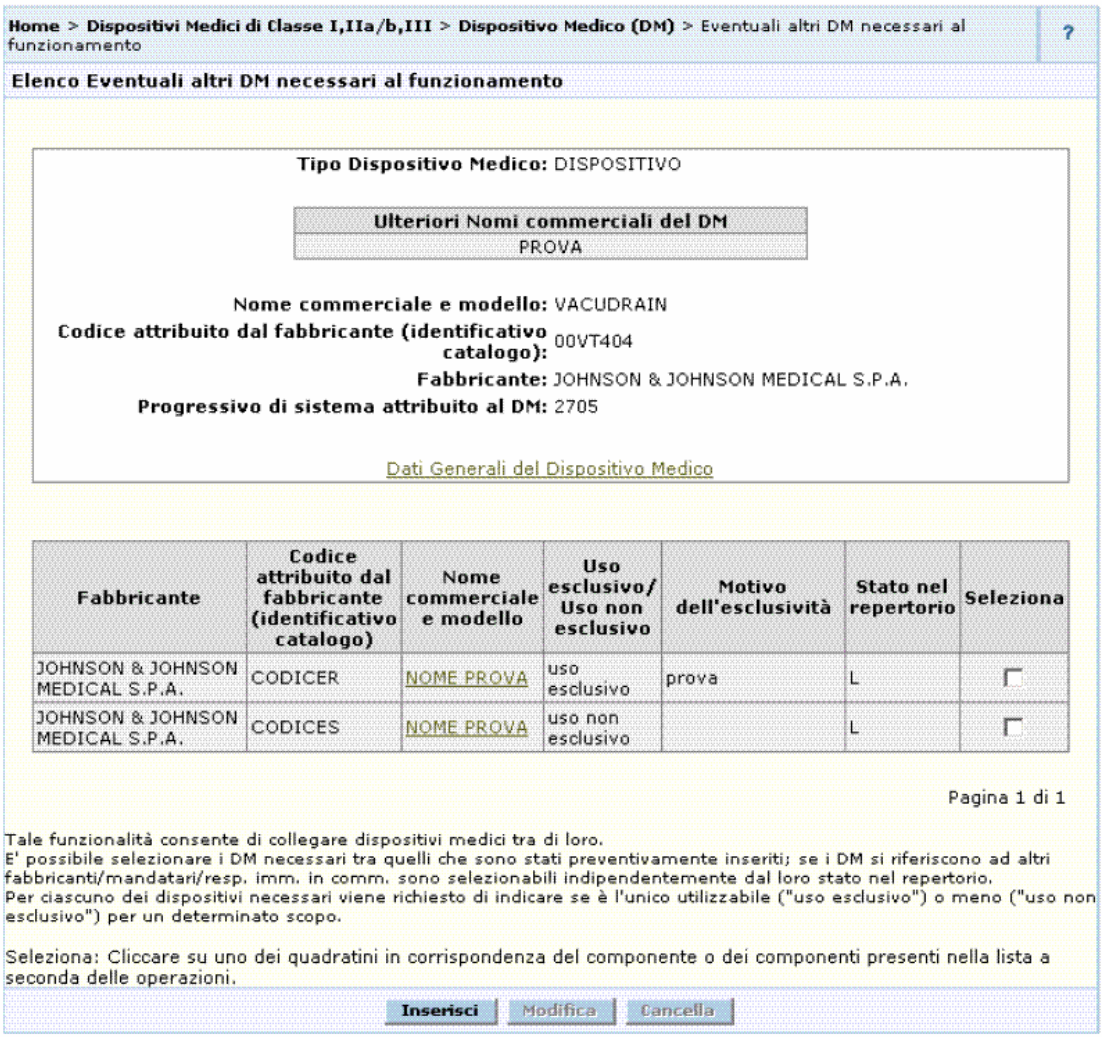
Page Name: GesDMNecessariLista

This page allows the user to link one DM to another DM, that are required for its functionality.

This page is accessible by the user in the following cases:

- During the insertion phase of the DM after the registration of the general data
- During the editing phase of the DM
- During the insertion phase of the DM by means of copying one that already exists in the system

In the upper section of the page, the principle data of the DM are displayed as well as the “Dati Generali del Dipositivo Medico” link which opens the page containing the general data of the DM.
In correspondence to the “Nome commerciale e modello” of each correlated DM, there is a link which allows the user to view the general data of the respective DM selected.



DM required Detail Fields

Field Name	Description
Fabbricante	Manufacturer of the DM required
Codice attribuito dal fabbricante (identicativo catalogo)	The code attributed by the manufacturer to the DM required
Nome commerciale e modello	The commercial name of the DM required
Uso esclusivo /Uso non esclusivo	Indicates if the DM to be linked, has an exclusive use regarding the “Father” DM
Motivo dell’esclusività	Reason for its exclusiveness
Stato nella base dati	Status of he DM in the database. This status can change in the following order: • L: in progress • V: Valid • P: Published

Operations available

Action	Description	Page name
Inserisci	Grants access to the DM search page of the DM to be linked	GesDMNecessariFormRicerca
Modifica	Grants access to the details of the linked DM (selected) in order to edit the data regarding the exclusiveness, or otherwise, of the association .	GesDMNecessariModifica
Cancella	Allows the association between the DM and the DM selected from the list to be removed	Same

Page Name: GesDMNecessariForm Ricerca

This page allows the user to search for DM to link up. At least one search margin is required.

In the upper section of the page, the principle data of the DM are displayed as well as the “Dati Generali del Dipositivo Medico” link which opens the page containing the general data of the DM.

Search Detail Fields

Field Name	Description
Progressivo di sistema attribuito al DM	Option to serch a Medical Device by its identification number assigned by the system during registration into the database
Tipo DM	Indicate the class of Medical device. There are three following types of DM: • Device • System • Kit
Fabbricante	The name or (or beginning thereof) of the Manufacturer of the DM can be specified
Nome commerciale e modello	The commercial name of the DM (or beginning thereof) can be specified
Codice attribuito dal fabbricante (identicativo catalogo)	The specific code attributed to the DM by the manufacturer
Classificazione CND	Indicates the national classification of the DM This field is cannot be edited. To select a CND classification, click on “cerca”; a

	look-up will open from which it will be possible to search for a CND classification by code and description.

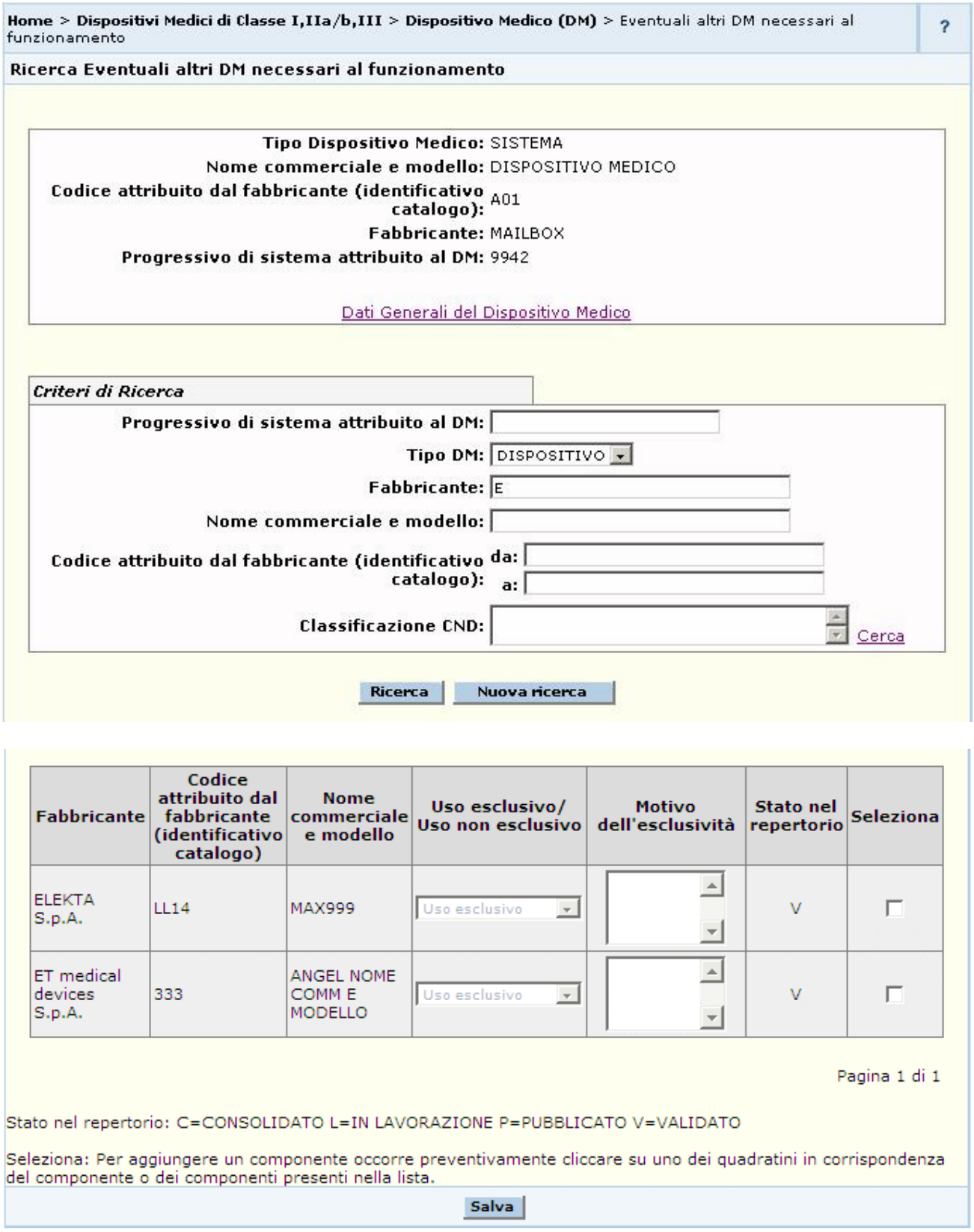
Operations available

Action	**Description**	**Page name**
Ricerca	Runs a search with criteria put in place and displays the DM list or list of Non-DM products that match the same criteria	GesDMNecessariDaAquistare
Reset	Clears the search criteria previously put in place	Same

Page Name: GesDMNecessariDaAquistare

This page displays a list of DM to be linked, according to the criteria put in place in the search page. In the upper section of the page, the principle data of the DM are displayed as well as the "Dati Generali del Dipositivo Medico" link which opens the page containing the general data of the DM.

Once the DM to be linked have been selected, The "Uso esclusivo/Uso non esclusivo" and "Motivo dell'esclusività" fields will automatically become unblocked.



Search Detail Fields

Field Name	Description
Progressivo di sistema attribuito al DM	Option to serch a Medical Device by its identification number assigned by the system during registration into the

	database
Tipo DM	Indicate the class of Medical device. The following are types of DM: • Device • System • Kit
Fabbricante	The name or (or beginning thereof) of the Manufacturer of the DM can be inserted
Codice attribuito dal fabbricante (identicativo catalogo) da/a	Range of codes which includes the product code assigned to the DM by the Manufacturer.
Nome commerciale e modello	The commercial name of the DM (or beginning thereof) as given by the Manufacturer, can be inserted
Classificazione CND	Indicates the national classification of the DM This field is cannot be edited. To select a CND classification, click on "cerca"; a look-up will open from which it will be possible to search for a CND classification by code and description.

List Detail Fields

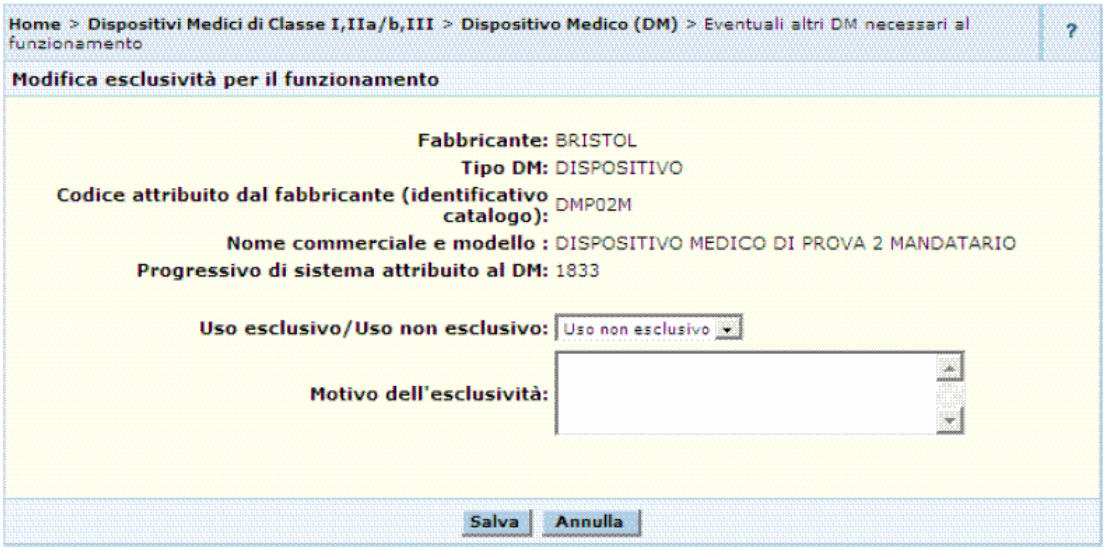
Field Name	**Description**
Fabbricante	the name of the Manufacturer of the DM
Codice attribuito dal fabbricante (identicativo catalogo)	The code attributed to the DM by the manufacturing company
Nome commerciale e modello	The name of the DM as given by the manufacturer
Uso esclusivo /Uso non esclusivo	Indicates if the DM to be linked, has an exclusive use, regarding the "Parent " DM
Motivo dell'esclusività	Reason for its exclusiveness
Stato nella base dati	The status of the DM in the database. It can change status in the following order: • L: Processing • V: Valid • P: Published

Operations available

Action	**Description**	**Page name**
Ricerca	Runs a search with criteria put in place and displays the DM list or list of Non-DM products that match the same criteria	Same
Reset	Clears the search criteria previously put in place	Same
Salva	Saves the actions carried out by the user	GesDmNecessariLista

Page Name: GesDMNecessariModifica

This page allows the user to view the details of a linked DM, by stating its principle data. From that page the data which stipulates the exclusiveness or otherwise of the association can be edited.



List Detail Fields

Field Name	Description
Fabbricante	The name of the Manufacturer of the DM
Codice attribuito dal fabbricante (identicativo catalogo)	Specific code attributed to the DM by the manufacturing company
Nome commerciale e modello	The name of the DM as given by the manufacturer
Uso esclusivo /Uso non esclusivo	Indicates if the DM to be linked, has an exclusive use, regarding the “Parent ” DM
Motivo dell’esclusività	Reason for its exclusiveness This field cannot be edited

Operations available

Action	Description	Page name
Salva	Saves the actions carried out by the user	GesDmNecessariLista
Annulla	Cancels the changes	GesDmNecessariLista

2.3.1.9 DM Editing

The edit feature of a DM in “In lavorazione” phase, can be activated upon the selection, from the DM list, of the device, whose information the user intends to edit

by clicking in the “Modifica” button. Following the completion of these actions, the general data page appears on which the side menu displays menu options which open the data page of each DM, in editable mode, in order to insert/edit the DM.
For the description of the data pages, see parg.4.1.3.1

2.3.1.10 View DM Data

The detailed information of a DM can be viewed by the following types of users:

1. Fab/Man/RIC/SD users, as regards their own inserted DM
2. DGFDM users, as regards all DM that are have the “validato” or “publicato” status

In order to view the data of a DM, both types of user must proceed as follows:

1. Run the DM search (by clicking on “Dispositivo Medico (DM)” in the menu, insert the search criteria by clicking on the “Ricerca” button), in order to select the desired DM
2. Click the “Visualizza” button to access the “Dati Generali” of the DM
3. Select the menu option corresponding to the specific information of the DM (Specifications data sheet, Documentation, sales data, System and Kit composition (Art2. should the medical device be a system or a kit) therefore accessing the DM data pages one by one in order to consult the information.

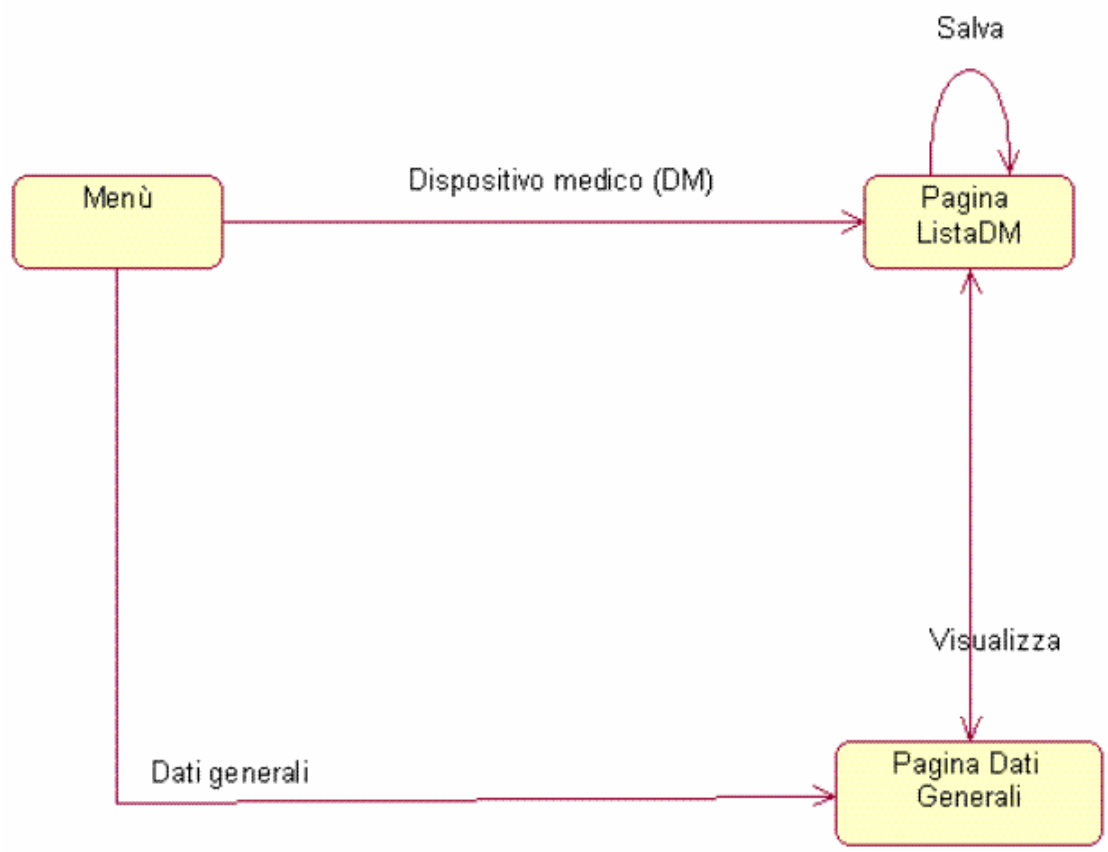
2.3.1.10.1 DM data page for consultation purposes of its details.

The data pages of a DM in read-only mode can be accessed by all users of the system and allows them to consult the information details of the DM selected on the “Pagina Lista DM” page.

The data pages are:

1. General Data Page
2. Specifications Page
3. Documentation Page
4. commercial data Page
5. System and Kit Composition (Para.3 Art.12)
6. Possible other DM necessary for its functionality

2.3.1.10.1.1 General Data

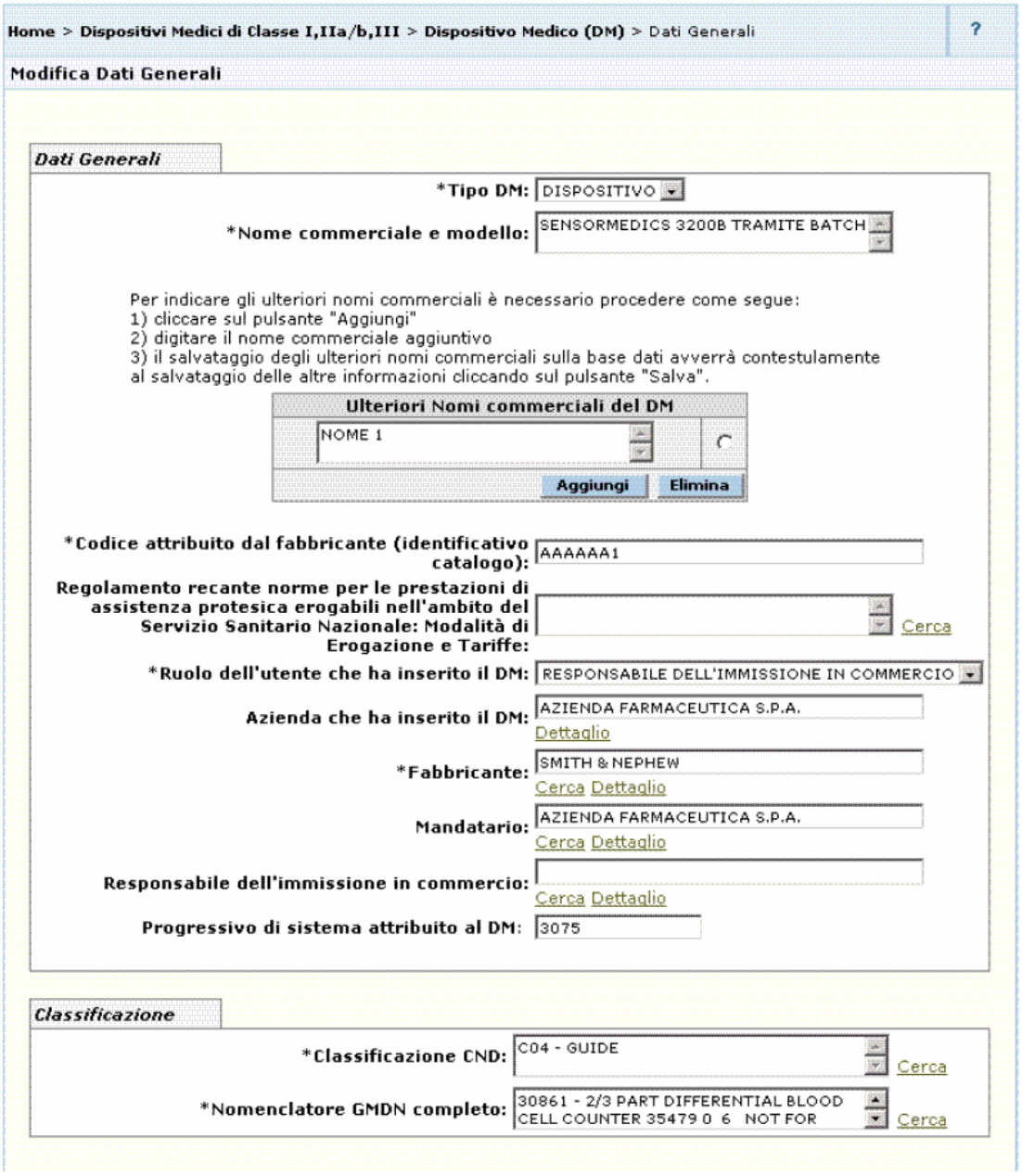


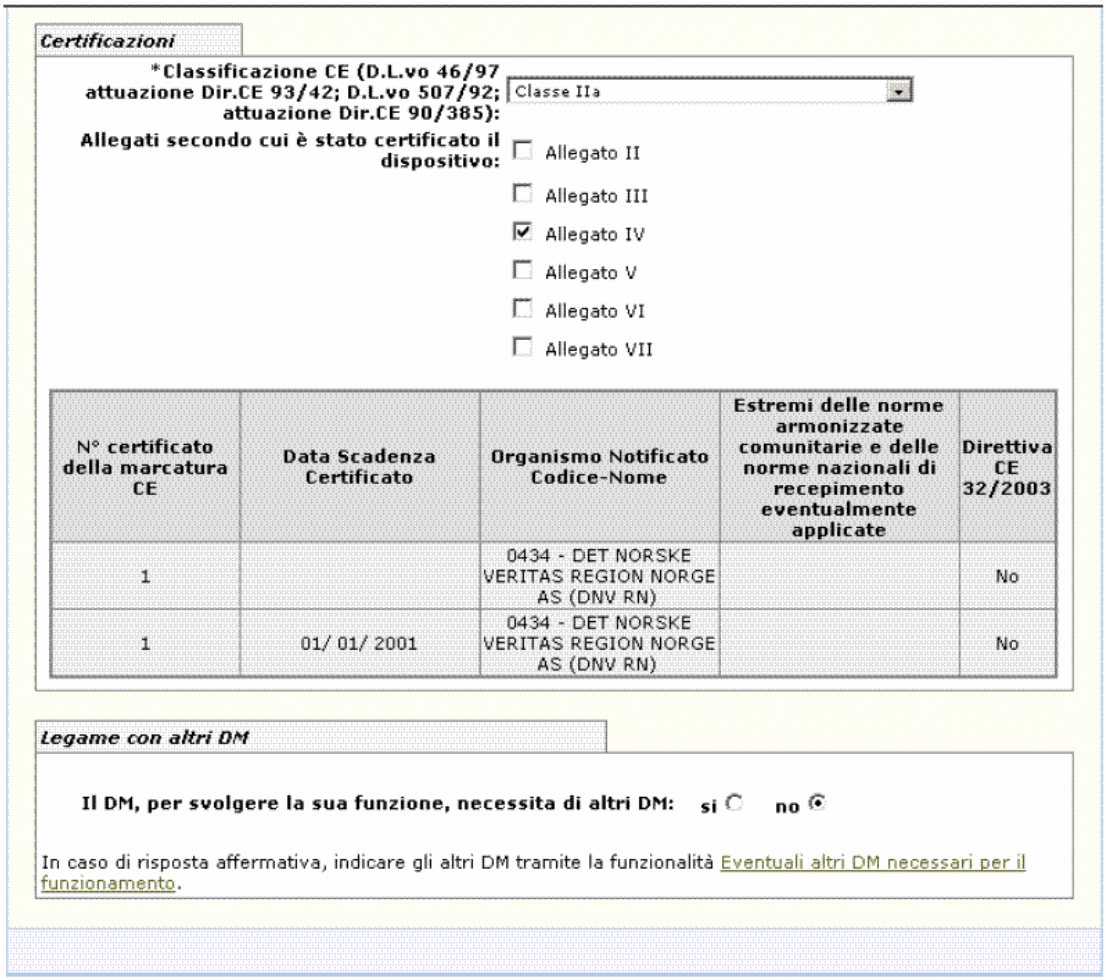
Page Name: PaginaDatiGenerali

This page allows the user to view the general data of a DM. The general data of a DM are subdivided in four areas:

- General data
- Data concerning classifications
- Data concerning certifications
- Links with other DM

In the “Legami con altri DM” box the “Eventuali altri DM necessari per il funzionamento” link allows the user to access the page with he list of other possible DM required for the functionality of the “Parent” DM.


Home > Dispositivi Medici di Classe I,IIa/b,III > Dispositivo Medico (DM) > Dati Generali
?
Modifica Dati Generali
Dati Generali
*Tipo DM: DISPOSITIVO
*Nome commerciale e modello: SENSORMEDICS 3200B TRAMITE BATCH
Per indicare gli ulteriori nomi commerciali è necessario procedere come segue:
1) cliccare sul pulsante "Aggiungi"
2) digitare il nome commerciale aggiuntivo
3) il salvataggio degli ulteriori nomi commerciali sulla base dati avverrà contestulamente al salvataggio delle altre informazioni cliccando sul pulsante "Salva".
Ulteriori Nomi commerciali del DM
NOME 1
Aggiungi
Elimina
*Codice attribuito dal fabbricante (identificativo catalogo): AAAAAA1
Regolamento recante norme per le prestazioni di assistenza protesica erogabili nell'ambito del Servizio Sanitario Nazionale: Modalità di Erogazione e Tariffe:
Cerca
*Ruolo dell'utente che ha inserito il DM: RESPONSABILE DELL'IMMISSIONE IN COMMERCIO
Azienda che ha inserito il DM: AZIENDA FARMACEUTICA S.P.A.
Dettaglio
*Fabbricante: SMITH & NEPHEW
Cerca Dettaglio
Mandatario: AZIENDA FARMACEUTICA S.P.A.
Cerca Dettaglio
Responsabile dell'immissione in commercio:
Cerca Dettaglio
Progressivo di sistema attribuito al DM: 3075
Classificazione
*Classificazione CND: C04 - GUIDE
Cerca
*Nomenclatore GMDN completo: 30861 - 2/3 PART DIFFERENTIAL BLOOD CELL COUNTER 35479 0 6 NOT FOR
Cerca



General DM data Detail Fields

Field Name	Description
Tipo DM	Indicate the class of Medical device. The following are types of DM: • Device • System • Kit
Nome commerciale e modello	Name of DM as given by the Manufacturer
Ulteriori Nomi commercali del DM	List of alternative commercial names that the DM has been called
Codice attribuito dal fabbricante (identicativo catalogo) da/a	Product code assigned to the DM by the Manufacturer.
Nomenclature Tariffario vigente	Name of DM according to the nomenclature charges in force

Ruolo dell'utente rispetto al DM	Indicates the role carried out by the user with respect to the DM. The user can adopt the following roles: - Manufacturer - Mandate Holder - Marketing Director - Other individual delegated by the Manufacturer
Fabb./Man./Resp.Imm.Comm./Altr.Sogg.Del.Fabbr.:	Indicates the Manufacturing company/Mandate Holder/Marketing Director/Other individual from the Manufacturer of the DM
Fabbricante	Name of the Manufacturer of the DM.
Progressivo di sistema attribuito al DM	Consecutive invoice number attributed to the DM by the system. If /R appears next to the consecutive number assigned to the DM by the system, it means that the DM has been registered on the index
Classifications	
Nomenclatore GMDN completo	Indicates the classification according to the GMDN(Global Medical Device Nomenclature) of the DM.
Classificazione CND	Indication of the National classification of the DM.
Certifications	
Classificazione CE (D.L.vo 46/97 attuazione Dir. CE 93/42; D.L.vo 517/92; attuazione Dir. CE 90/385	Indication of the EC classification of the DM. The EC classification can adopt the following principles: - Class I with measurement functions - Class I non sterile and or measurement functions - Class I sterile - Class I sterile with measurement functions - Class IIa - Class IIb - Class III - Active implant devices
Allegati secondo cui è stato marcato il dispositivo	Indication of the attachments according to which the device has been marked.
N Certificato della marcatura CE	Identification number of the EC stamp
Data Scadenza Certificate	Expiry date of Certificate
Organismo Notificato - Nome	Indication of the code and name of the organisation notified.
Estremi delle norme armonizzate comunitarie e delle norme nazionali di recepimento eventualmente applicate	Indication of the Essential details of the National and Community norms acknowledged during the fabrication of the DM
Direttiva CE 32/2003	States whether or not the certificate should be issued in compliance with EC Directive 32/2003
Links to other DM	
Il DM, per svolgere li sua funzione, necessita di altri DM	Indicates whether or not the DM requires other DM for it's fuctionality.

Operations available: None

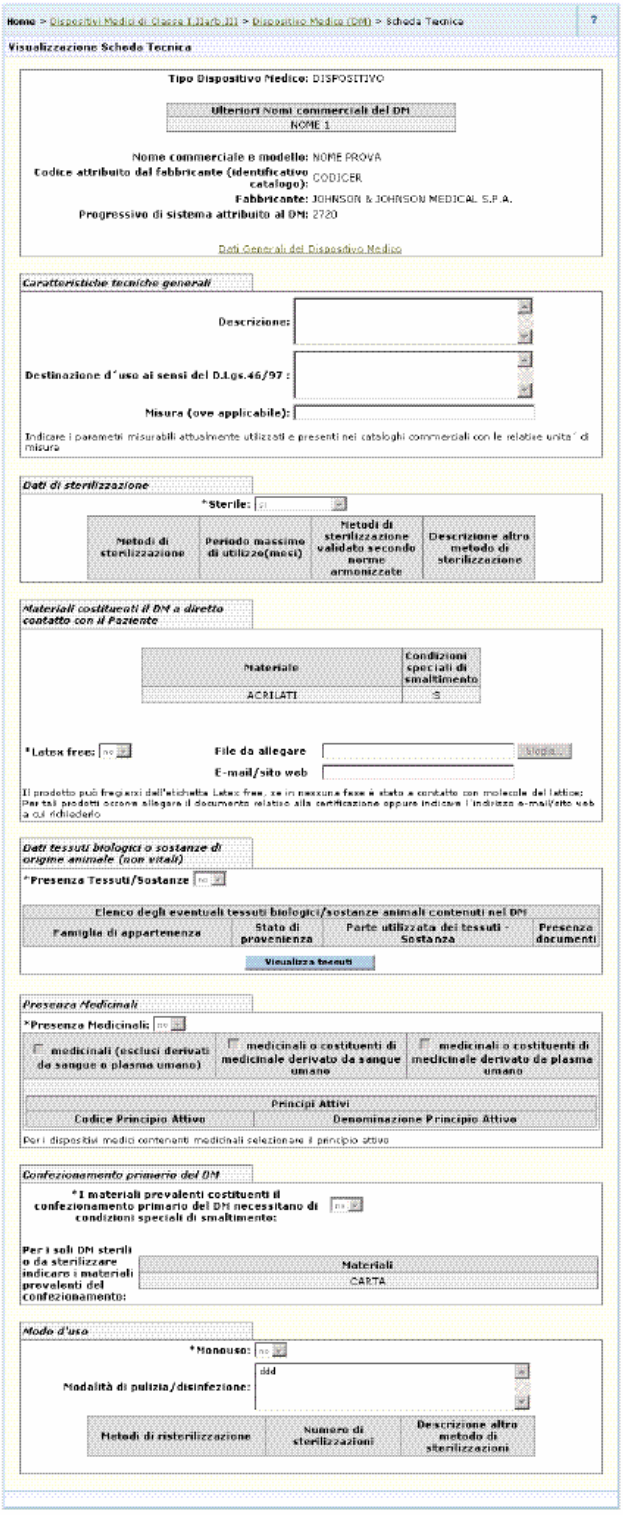
2.3.1.10.1.2 Specifications Data Sheet

Page Name: Specifications Data Sheet

This page allows users to view the technical data of a DM. The data on a DM specifications Data Sheet are subdivided in the following areas:

- General technical characteristics
- Sterilisation date
- Material that the DM is made up of that come in direct contact with the Patient. (Each material is marked as to whether or not specific disposal is required)
- Biological tissues or substances of animal origin(not vital) Data. (The family of origin, original condition, the part utilised, the presence or otherwise of documentation associate with the tissue are all specified.
- Presence of medicinal products (the code name of each active ingredient is stated)
- Primary packaging of DM (with the list of materials that form it)
- Directions for use

In the upper section of the page, the principle data of the DM are displayed as well as the “Dati Generali del Dipositivo Medico” link which opens the page containing the general data of the DM.



DM Specifications Data Fields

Field Name	Description
General technical characteristics	
Descrizione	Description of the general technical characteristics of the DM

Destinazione d'uso ai sensi delD.Lgs.46/97	Intended use In accordance with the D.Lgs.46/97
Misura (ove applicabile)	Indication of the measurable criteria actually used and present in commercial catalogues with the corresponding unit of measurement of the DM
Sterilisation data	
Sterile	Indication of whether or not the DM is sterile
Metodo di sterilizzazione	Method used to sterilise the DM. This field is required if the "Sterile" field is marked "Si"
Specify if another Metodo di sterilizzazione is used	Description of the sterilisation method if it is not already present on the loaded list previously. This field is required if the "Metodo di sterilizzazione" field is marked "Altro"
Metodo di sterilizzazione validato secondo	The method of sterilisation can be validated: - according to the harmonised norms - other. This field is required if the "Sterile" field is marked "Si"
Periodo massimo di utilizzo	Maximum length of use of the DM. This field is required if the "Sterile" field is marked "Si"
Material contained in the DM that comes in direct contact with the Patient	
Latex free	Indication as to whether or not the DM contains latex.
Fila da allegare	File containing the Latex free certification.
E-mail/Sito web	Indication of email or web site where the Latex free certificate can be requested.
Data of biological tissue or substances of animal origin (not vital)	
Presenza Tessuti/Sostanze	Indication of whether or not the DM contains Biological tissue/animal substances
Medicinal products Present	
Presenza Medicinali	Indication as to whether or not the DM contains medicinal products
Medicinali (esclusi derivati da sangue o plasma umano)	Indicates if there are medicines present in the DM (excluding those derived from blood or human plasma).
Medicinali o cosituenti di medicinale derivati da sangue umano	Indicates if there are medicines present in the DM derived from human blood).
Medicinali o cosituenti di medicinale derivati da plasma umano	Indicates if there are medicines present in the DM derived from human plasma).
Primary packaging of the DM	
Prevalent material making up the primary packaging of the DM that require specific	Indicates if the primary packaging of the DM must be disposed of in a specific manner

disposal	
Directions for use	
Monouso	Indicates whether or not the DM is disposable
Metodo di re-sterilisation	Method used to re-sterilise the DM. This field is required if in the “Monouso” field it was marked “No”
Specify existing alternative Metodo di re-sterilisation	Description of method of re-sterilisation if it is not found on the previously loaded list. This field is required if in the “Metodo di Re-sterilizzazione” field it was marked “Other”
Modalità di pulizia/disinfezione	Method used to clean/disinfect the DM. This field is required if in the “Monouso” field it was marked “No”
Numero di sterilizzazione consentite(ove stabilito)	Maximum number of times it is permitted to sterilise a DM. This field is required if in the “Monouso” field it was marked “No”

Operations available

Action	Description	Page name
Visualizza tessuti	Grants the user access to a window where he can view the detailed information of each biological tissue/animal substance associated with the DM	LookUpTessuti

Page Name: LookUpTessuti

This page allows the user to view the data on each biological tissue/animal substance associated with the DM. In particular, this window permits the user to download or view a link to a site where the information of each tissue/substance can be found regarding:

- The origin of the tissue – substance
- The treatment and deactivation methods
- Other documentation provided by the Health Authority

LookUpTessuti Detail Fields

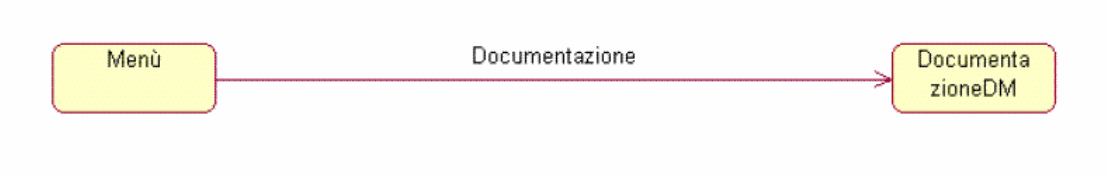
Field Name	Description

Famiglia di appartenenza	Family of origin of the biological tissue/animal substance contained in the DM
Altra Famiglia	Description of the family of origin of the biological tissue/animal substance contained in the DM This field is required if the corresponding "Famiglia di Appartenenza" was indicated as "Altro
Stato di provenienza	Original condition of the biological tissue/animal substance
Parte utilizzata dei tessuti	Parts of tissue used in DM
Altra parte utilizzata	Description of the parts of the biological tissue/animal substance used in the DM This field is required if the corresponding "parte utilizzata dei tessuti" was marked "Altro"
Disponibilità dei doc. sulla provenienza del tessuto – sostanza	Indication of the presence of documentation on the origin of the tissue – substance
Fila da allegare (in riferimento al campo"Disponibiltà de doc. Sulla provenienza del tessuto – sostanza")	File containing the documentation on the origin of the tissue – substance.
Indirizzo e-mail/sito web (in riferimento al campo "Disponibiltà dei doc. Sulla provenienza del tessuto – sostanza")	Email address/Web site from which the origin of the tissue – substance can be traced.
Disponibilità dei doc. sui metodi di trattamento e inattivazione	Indication of the presence of documentation on methods of treatment and deactivation
Fila da allegare (in riferimento al campo"Disponibiltà dei doc. sui metodi di trattamento e inattivazione")	File containing the documentation on methods of treatment and deactivation.
Indirizzo e-mail/sito web (in riferimento al campo"Disponibilità dei doc. sui metodi di trattamento e inattivazione"	Email address/web site where the documentation on methods of treatment and deactivation can be found.
Disponibilità dei doc. delle Autorità Sanitarie	Indicates the presence of documentation provided by the Health authority regarding the tissues/substances selected.
Fila da allegare (in riferimento al campo"Disponibilità dei doc. delle Autorità Sanitarie")	File containing the documentation provided by the Health authority regarding the tissues/substances selected.
Indirizzo e-mail/sito web (in riferimento al campo"Disponibilità dei doc. delle Autorità Sanitarie")	Email address/web site where the documentation provided by the health authority regarding the tissue/substance selected can be found

Operations available

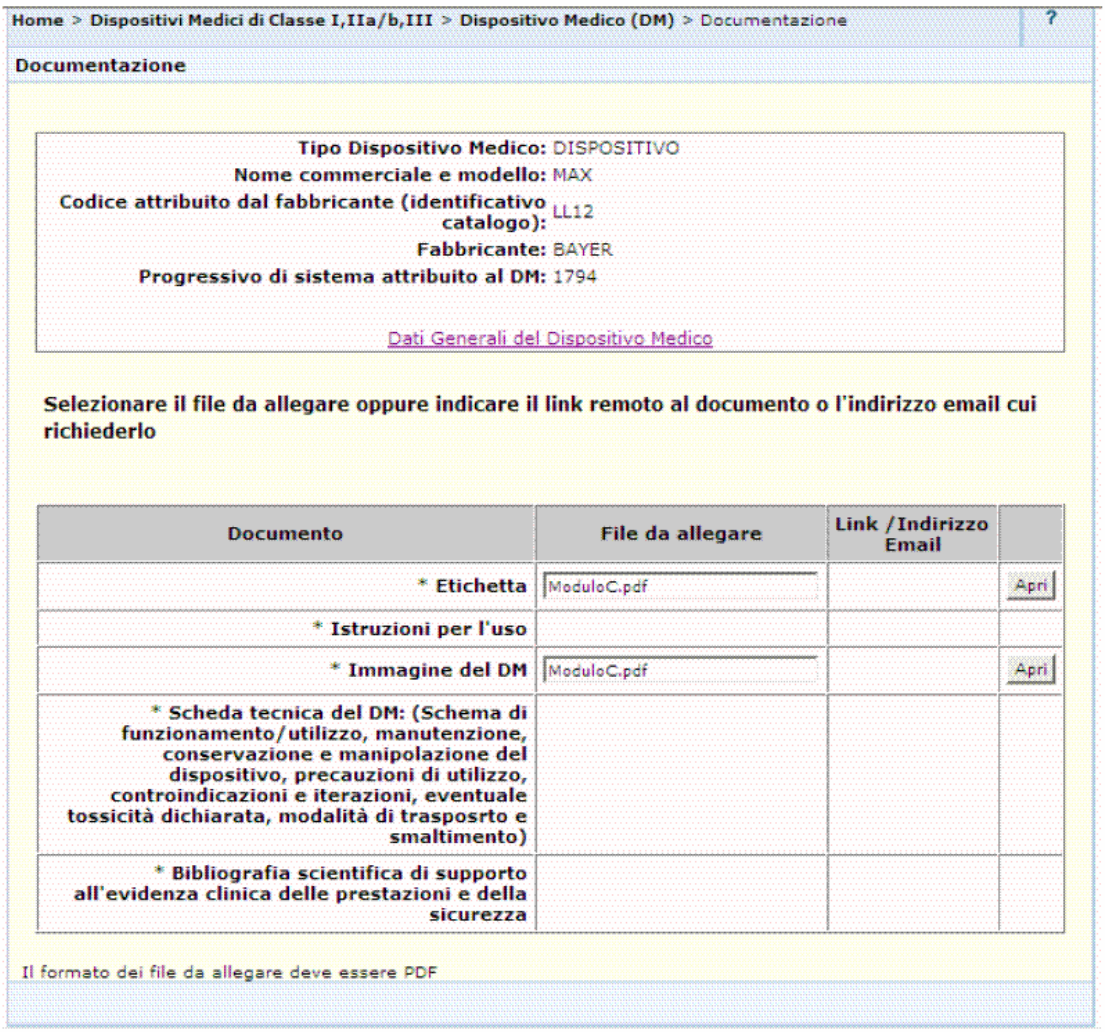
Action	Description	Page Name
Visualizza	Displays a box in which the user can view information regarding biological tissue/animal substance selected.	Same
Chiudi	Closes the window	Scheda Tecnica

2.3.1.10.1.3 Documentation



Page Name: DM Documentation

This page allows the user to view the documentation attached to a DM ad therefore to download the files attached.
In the upper part of the page, the principle data of the DM are displayed as well as the "Dati Generali del Dipositivo Medico" link which opens the page containing the general data of the DM.



Documentation Detail Fields

Field Name	Description
Etichetta	File containing the label of the DM.
Istruzioni per l'uso	File containing the direction for use of the DM
Immagine del DM	File containing the image of the DM. Not obligatory.
Scheda tecnica del DM: (Schema di funzionamento/utilizzo, manutenzione, conservazione e manipolazione del dispositivo, precauzioni di utilizzo, controindicazioni e iterazioni, tossicità dichiarata, modalità di trasporto e smaltimento)	The file containing the specifications of the DM or alternatively, a link to the site where the same information may be found.

Bibliografia scientifica di supporto all'evidenza clinica delle prestazioni e della sicurezza	File containing the Scientific bibliography, supporting the clinical evidence of the effectiveness and the safety of the DM or alternatively a link to a site where the same information may be found

Operations available

Action	Description	Page Name
Apri	Allows the user to download the attached document	

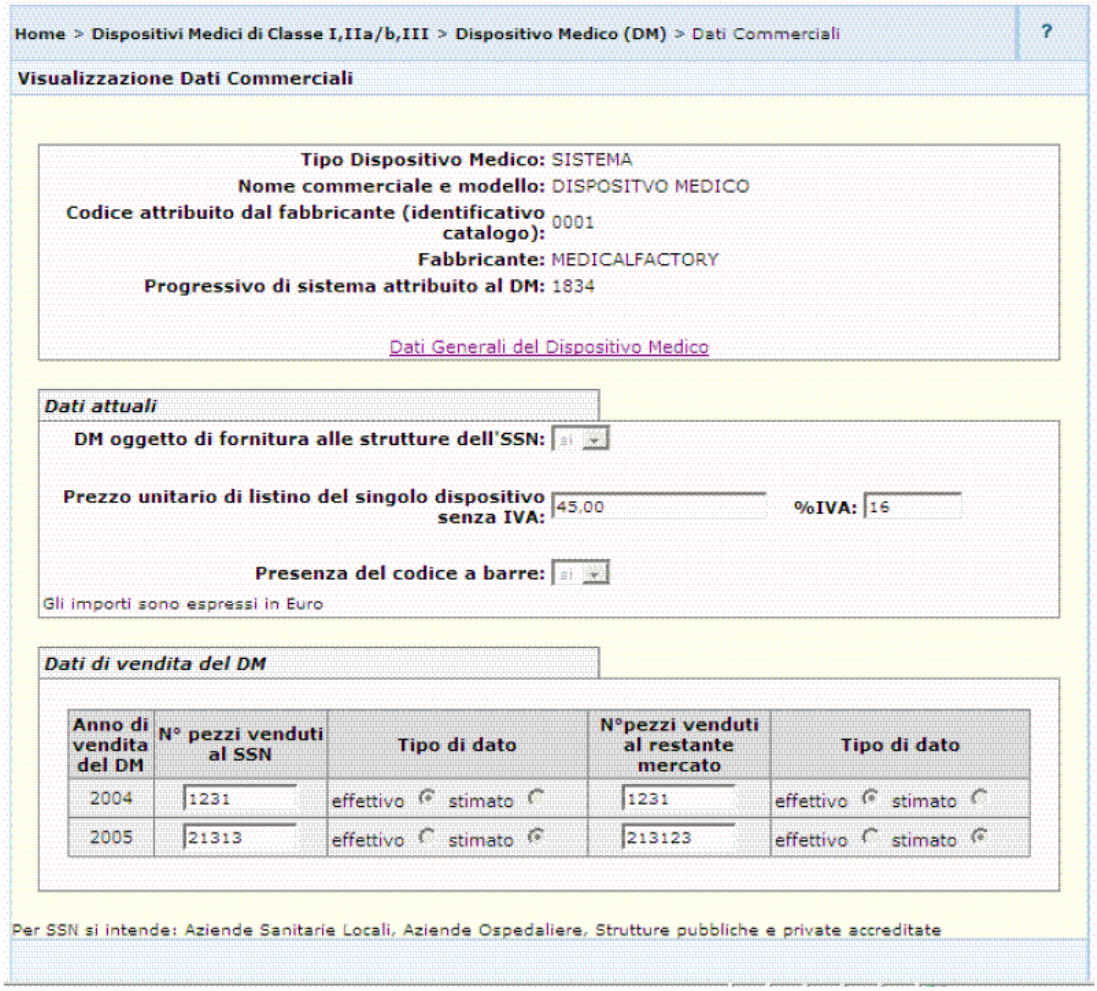
2.3.1.10.1.4 Commercial Data

Page Name: DatiCommercialiDM

This page allows the user to insert/edit the commercial data of a DM. The commercial data of a DM are subdivided into two areas.

- Current data of the DM
- Annual sales details of the DM

In the upper section of the page, the principle data of the DM are displayed as well as the "Dati Generali del Dipositivo Medico" link which opens the page containing the general data of the DM.



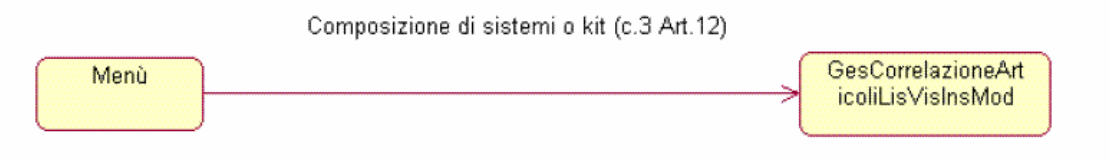
Commercial data Fields

Field Name	**Description**
Current data	
DM oggetto di fornitura alle strutture dell'SSN	Indication whether or not the DM is destined to be used by the SSN
Prezzo unitario di listino del singolo dispositivo senza IVA	Unit sale price of a DM excluding tax
%IVA	Indication of the IVA applied to the DM
Presenza del codice a barre	Indication as to whether or not the DM bears a barcode
DM Sales data	
Anno di vendita del DM	Indication of the year the DM was sold
N° pezzi venduti al SNN	Indication of the number of pieces sold to the National Health Service.
Tipo di dato	Indication of the type of data (No. of pieces sold to the SSN) either estimated or exact

N° pezzi venduti al restante mercato	Indication of the number of DM pieces old (excluding pieces sold to the SSN).
Tipo di dato	Indication of the type of data (No. of pieces sold to the rest of the market) either estimated or exact

Operations available:None

2.3.1.10.1.5 Systems and Kit contents (Para.3 Art.12)



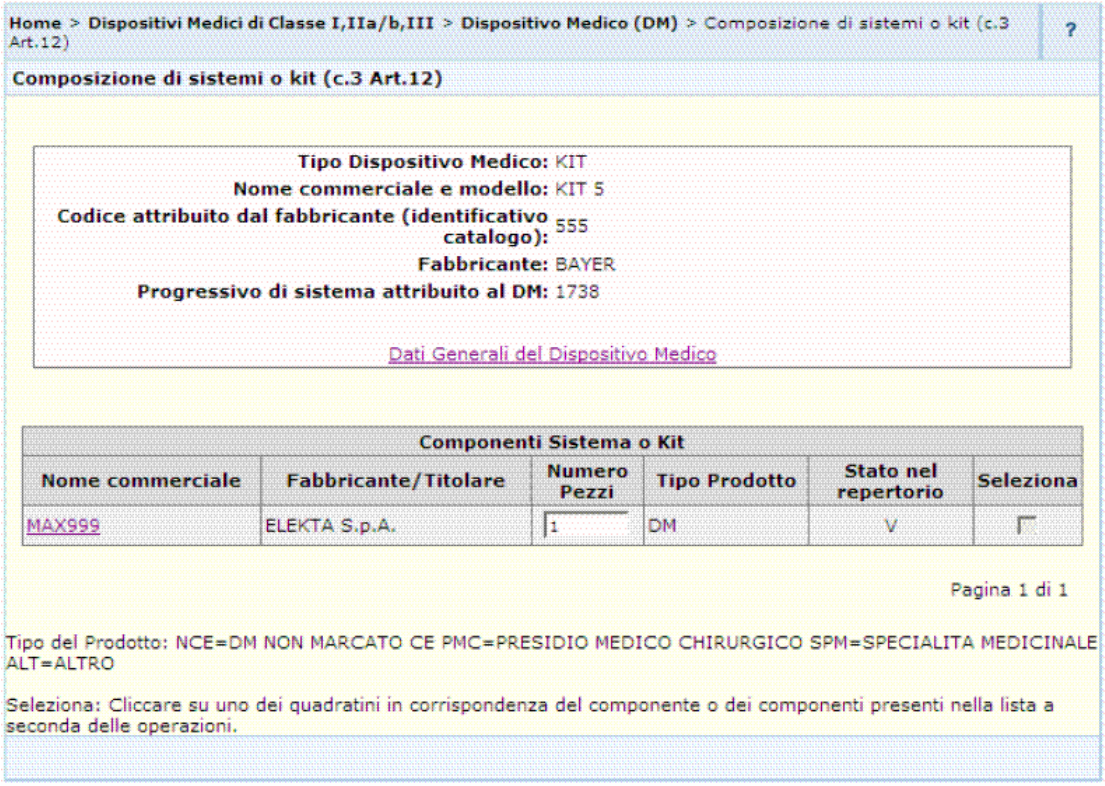
Page Name: GesCorrelazioneArticoliLisVisInsMod

This page allows the user to view the list of components of a system or kit in accordance with Para.3 Art.12. The components of a system or kit according to Para.3 Art.12, can be 3 types:

- CE marked DM
- Non -CE marked DM
- Non -DM articles

The commercial name of every system or kit component has a corresponding link which opens a window where the principle information of the selected component are synthesised.

In the upper section of the page, the principle data of the DM are displayed as well as the “Dati Generali del Dipositivo Medico” link which opens the page containing the general data of the DM.

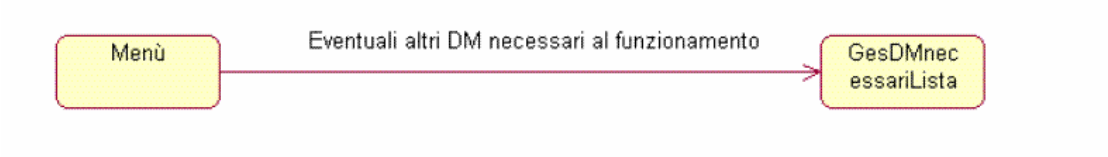


Component list Detail Fields

Field Name	**Description**
Nome Commerciale	Commercial name of the component. The commercial name has a corresponding link which opens a window where the detailed information of the selected component.
Fabbricante/Titolare	Indication of the Manufacturer/Title holder of the component.
Numero pezzi	Indication of the number of pieces of the component the system or kit requires.
Tipo prodotto	Indication of the component type. The following types are possible: - DM (Medical Device) - NCE (Non-CE marked DM) - PMC (Medical and surgical aids) - SM Medicines - ALT (Other Non-DM type of Article)
Stato nella base dati	The status of the DM in the database. The status can be changed in the following order: • L: Processing • V: Valid • P: Published

Operations available: None

2.3.1.10.1.6 Other possible DM required for its functionality

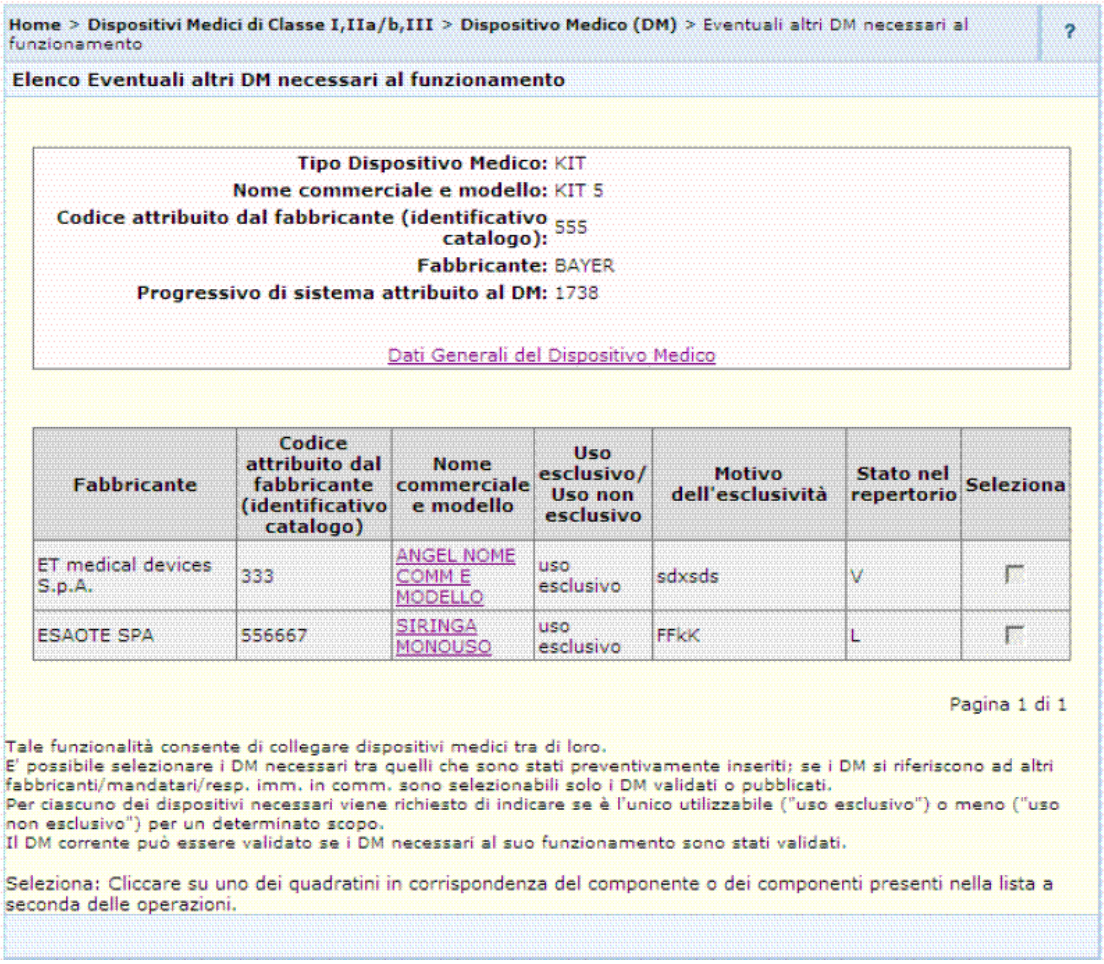


Page Name: GesDMnecessariLista

This page allows the user to view the list of DM required for the functionality of a "Parent" DM.

In the upper section of the page, the principle data of the DM are displayed as well as the "Dati Generali del Dipositivo Medico" link which opens the page containing the general data of the DM.

In correspondence to the "Nome commerciale e modello" of each correlated DM, there is a link which allows the user to view the general data of the respective DM selected.



DM required Detail Fields

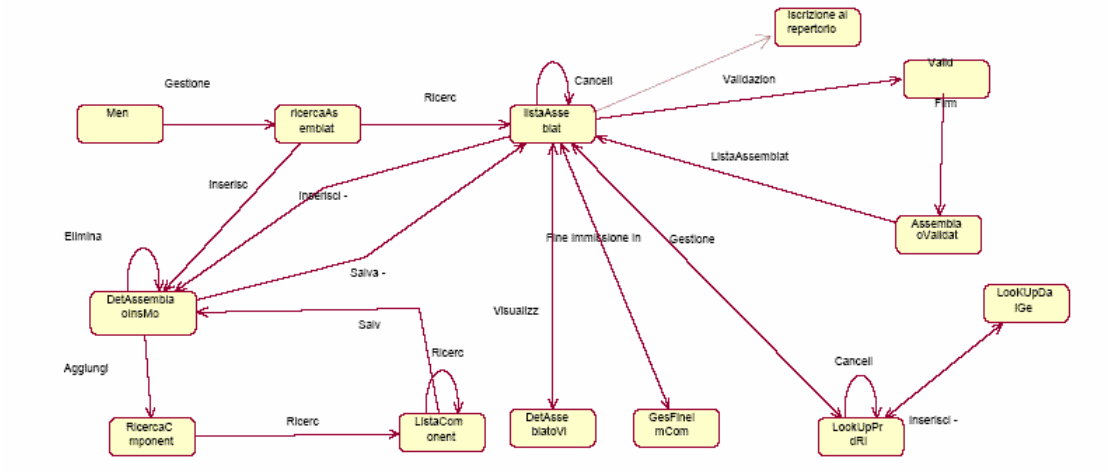
Field Name	**Description**
Fabbricante	Manufacturer of the DM required
Codice attribuito dal fabbricante (identicativo catalogo)	The code attributed by the manufacturer to the DM required
Nome commerciale e modello	The commercial name of the DM required
Uso esclusivo /Uso non esclusivo	Indicates if the DM to be linked, has an exclusive use regarding the “Parent” DM
Motivo dell’esclusività	Reason for its exclusiveness
Stato nella base dati	Status of he DM in the database. This status can be changed in the following order: • L: in progress • V: Valid

	• P: Published

Operations available: None

2.3.2 Menu option “Sistemi o kit assemblati (c.2 Art.12)”

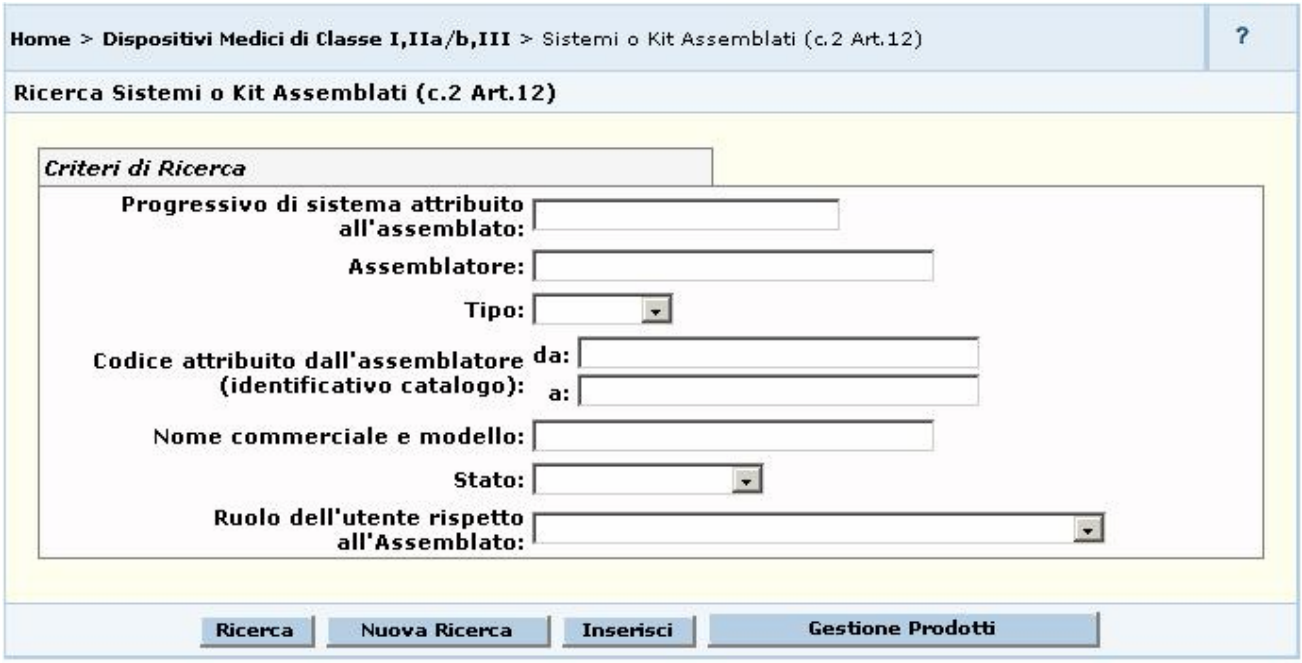
Screen flowchart:



2.3.2.1 Assembled device search

After selecting “Gestione assemblati” from the menu, a page appears that allows the user to put criteria in place, to run a search of the assembled systems or kits, according to Para.3 Art 12. To run the search of the assembled devices, it is necessary to enter at least one search parameter.

If the user uses the “Tipo” as a search parameter, choosing between “Sistema” or “Kit”, the page refreshes displaying another search margin “Tipo Assemblato”.



Search Detail Fields

Field Name	Description
Progressivo di sistema attribuito all'assemblato	Option to serch an Assembled device by its identification number assigned by the system during registration into the database.
Assemblatore	Option to specify the name (or the beginning) of the Assembler
Tipo	Type of Assembled device. The user has the option to choose between two types: • System • Kit
Codice attribuito dall' assemblatore (identificativo catalogo) da/a	A range of codes which includes the product code assigned to the assembled system or kit by the assembler.
Nome commerciale e modello	Option to specify the commercial name (or beginning) of the system or kit given by the assembler
Assembled Tipo	The list contains the types of assembled devices. It varies based n the choice made in the corresponding "Tipo" field. Therefore, two distinct types of system and kits exist.
Stato	Option to serch an Assembled device by its current status into the system ("In lavorazione", "Consolidato", "Validato", "Pubblicato").
Ruolo dell'utente rispetto all'Assemblato	Option to serach an Assembled device by the role carried out by the user with respect to it ("Assemblatore", "Mandatario", "Responsabile dell'immissione in commercio", "Altro soggetto delegato dal fabbricante")

Operations available

Action	Description	Page name

Ricerca	Runs a search with criteria entered and displays the assembled system or kit that match that criteria.	ListaAssemblati
Reset	Clears the search criteria previously put in place	Same
Inserisci	Grants access to the systems and kits data entry page	DetAssemblatoInsMod
Gestione Prodotti	Opens a window where the user has the option to manage (insert, edit, delete, view) Non-DM articles; type “Altro”	LookUpRicercaProdotti.

2.3.2.2 Assembled device list

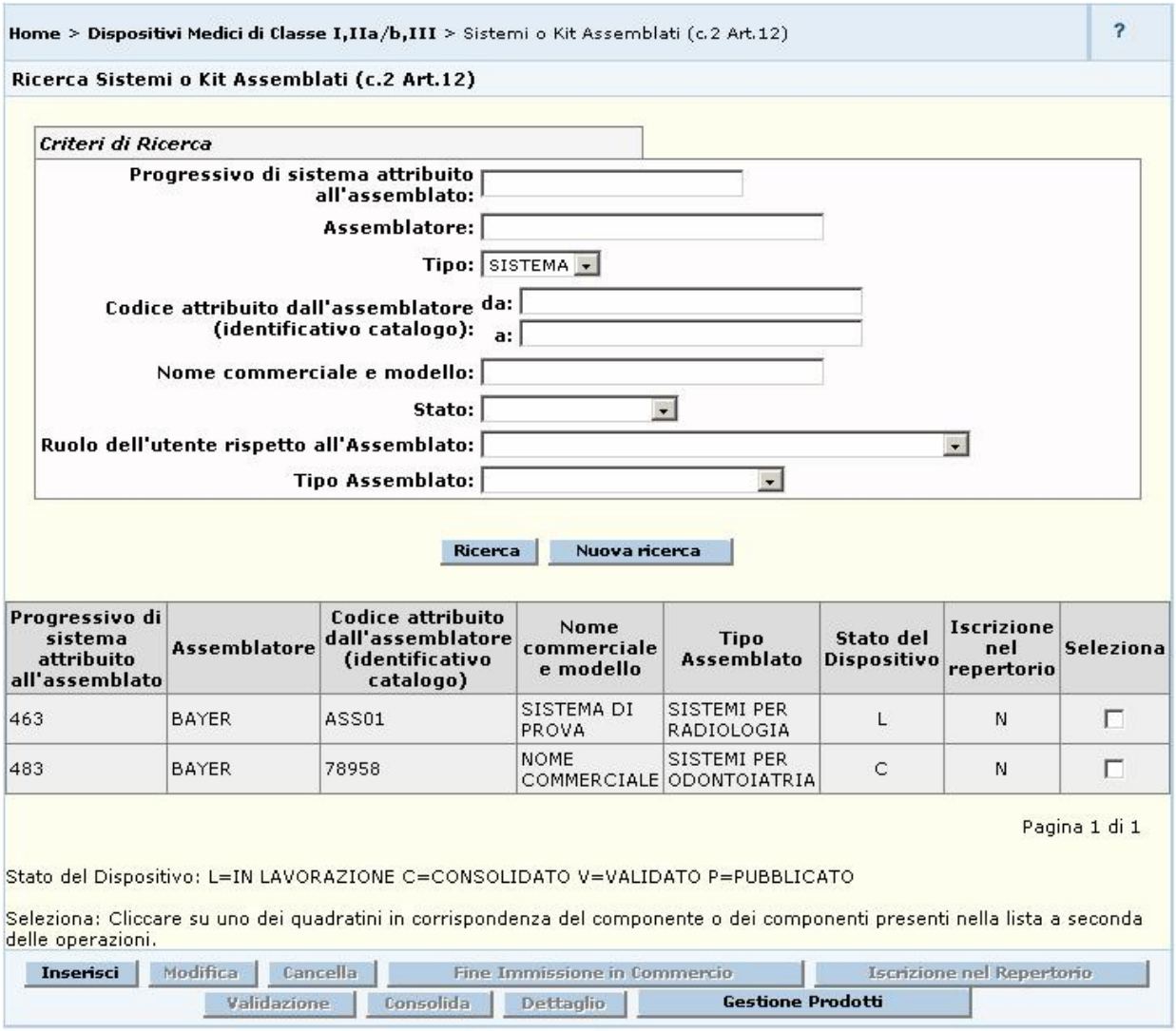
This page allows the user to view the list of assembled system and kits based on the search criteria entered.
The following information is available on each system and kit:

- Identification number assigned to the Assembled device by the system
- Assembler
- Identification code given by the assembler (identification catalogue)
- Commercial name and model of the assembled device
- Type of assembled device
- Status in the database

The list of assembled devices changes depending on the criteria stipulated as well as the user connected:

a Manufacturer/mandate holder/marketing director user, only sees the assembled devices which he inserted, regardless of their status in the database; on this page the following actions can be carried out:

- Run new search
- Insert a new assembled device
- Edit an assembled device in the “In lavorazione” stage
- Delete an assembled device in the “In lavorazione” stage
- Insert the off-market date of a “Validato” or “Pubblicato” assembled device.
- Validate an assembled device
- Register the assembled device on the index



Search Detail Fields

Field Name	Description
Progressivo di sistema attribuito all'assemblato	Option to serch an Assembled device by its identification number assigned by the system during registration into the database.
Assemblatore	Option to specify the name (or the beginning) of the Assembler
Tipo	Type of Assembled device. The user has the option to choose between two types: • System • Kit
Codice attribuito dall' assemblatore (identificativo catalogo) da/a	Range of codes which includes the product code assigned to the assembled system or kit by the assembler.
Nome commerciale e modello	Option to specify the commercial name (or beginning) of the system or kit the assembler has given

Assembled Tipo	Such search criteria are visible only after having set out the "Tipo" field. The list contains the types of assembled devices. It varies based on the choice made in the corresponding "Tipo" field. Therefore, distinct types of system and kits exist.
Stato	Option to serch an Assembled device by its current status into the system ("In lavorazione", "Consolidato", "Validato", "Pubblicato").
Ruolo dell'utente rispetto all'Assemblato	Option to serach an Assembled device by the role carried out by the user with respect to it ("Assemblatore", "Mandatario", "Responsabile dell'immissione in commercio", "Altro soggetto delegato dal fabbricante")

Assembled Devices List Detail Fields

Field Name	**Description**
Progressivo di sistema attribuito all'assemblato	Identification number assigned to the Assembled device by the system during its registration into the database.
Assemblatore	Name of the Assembler
Codice attribuito dall' assemblatore (identificativo catalogo) da/a	Product code assigned to the assembled system or kit by the assembler (catalogue identification number).
Nome commerciale e modello	Commercial name of the system or kit the assembler has given
Assembled device Tipo	Indication of the type of assembled device
Stato nella base dati	The status of the assembled device in the database. The status can change in the following order: • L: Processing • V: Valid • P: Published

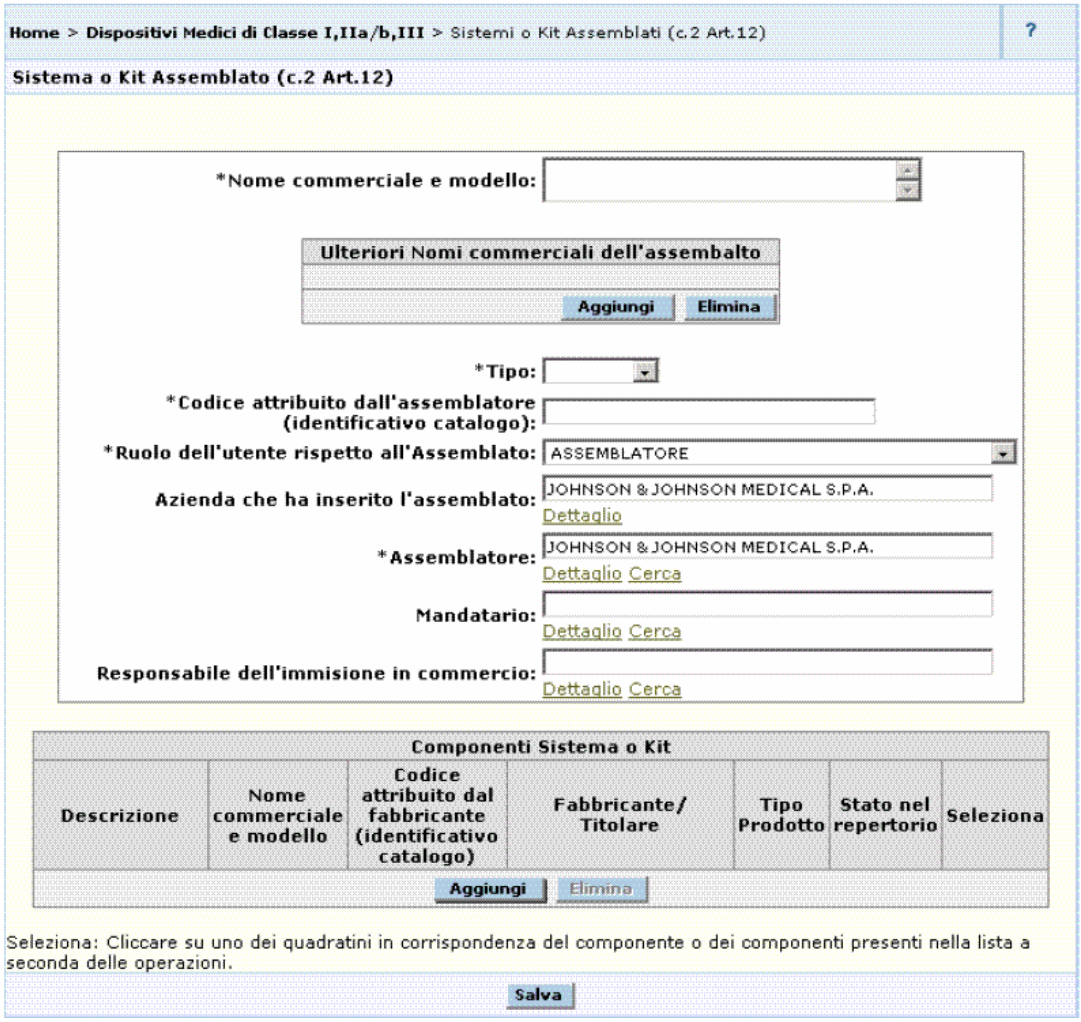
Operations available

Action	**Description**	**Page name**
Ricerca	Runs a search with criteria entered and displays the list of assembled systems or kits that match that criteria.	Same
Reset	Clears the search criteria previously put in place	Same
Inserisci	Grants the user access to the insertion page of the assembled systems and kits. (Only visible by "FABBRICANTEDM" users)	DetAssemblatoInsMod
Modifica	Allows the user to access the data page of the assembled system or kit selected in order to edit its details	DetAssemblatoInsMod
Cancella	Allows user to delete the system or kit, "In lavorazione", selected	Same

Validazione	Activates the signature page through which the user has the option to validate one or more system or kit in the "Consolidato" stage. (Only visible by "FABBRICANTEDM" users). Changing the status of the system or kit does not occur simultaneously with the "Validazione" action; it is necessary to wait a few moments to verify the successful completion of the process. Should any errors occur during the validation, they will be reported on the activity list, otherwise the system or kit selected will be marked with a V symbol for "Validato	Valida
Fine immissione in commercio	Grants access to the insertion page of the off-market date of "Validato" or "Pubblicato" system or kit selected. (Only visible by "FABBRICANTEDM" users).	GesFinProd
Consolida	Allows the user to confirm a system or kit in "in Lavorazione" status. The "Consolida" action displays the page containing the list of systems and kits in the approval phase, specifying whether the process has been activated or not. Should the process result negative, this will be stated in the activity list, otherwise the state of the system or kit will change to C, that is "Consolidato"	
Visualizza	Grants the user access to the data page of the system or kit selected, in read-only mode	DetAssemblatoVis
Gestione Prodotti	Opens a window where the user has the option to manage (insert, edit, delete, view) Non-DM articles; type "Altro".	LookUpRicercaProdotti.

2.3.2.3 DetAssemblatoInsMod

This page allows the Fab/Man/RIC/ASD user to insert/edit details concerning a system or kit.
In the insertion/editing phase of an assembled device two components must be added , one of which must be a DM
Corresponding with the "Nome commerciale e modello" field of each component of the assembled device, a link is provided which allows users to view additional information regarding the component selected.



Assembled Device Data Fields

Field Name	Description
Nome commerciale e modello	Name of the system or kit the assembler has given
Alternative Commercial name for DM	List of alternative commercial names that the DM has been called
Tipo	Type of assembled device. The user can choose between two types • System • Kit
Codice attribuito dall' assemblatore	Indication of product code assigned to the system or kit by the Assembler.

(identificativo catalogo)	
Ruolo dell'utente rispetto all'assemblato	Indicates the role carried out by the user with respect to the assembled device. The user can adopt the following roles: • Assembler • Manufacturer • Mandate Holder • Marketing Director • Other individual delegated by the Manufacturer In the insertion phase, the Assembler is set to appear by default.
Fabb./Man./Resp.Imm.Comm./Altr.Sogg.Del.Fabbr.:	Indicates the Manufacturing company/Mandate Holder/Marketing Director/Other individual from the Manufacturer of the DM
Assemblatore	Name of the assembler of the assembled system or kit. If the user has selected the assembler role with respect to the assembled device, the system automatically chooses the manufacturer entered by the user in the "Gestione Dati Azienda" page, Should the user choose a role other than assembler, he may select an assembler by clicking on the "Cerca" link; a look-up will Open where the user has the option to select the assembler desired.
Mandatario	Name of Mandate Holder of the assembled system or kit. If the user has selected the role of Mandate holder, regarding the assembled device, the system will automatically display the user's company, as Mandate holder as stipulated in the "Gestione Dati Azienda" feature. He can select the Mandate holder by clicking on the "Cerca" link; a look-up will open where the user has the option to search for and select a Mandate holder. The mandate holder may be selected only if the assembled device is legally registered in a non EU country.
Responsabile dell'immissione in commercio	Name of Marketing Director of the assembled system or kit. If the user has selected the role of Marketing Director of the assembled device, the system therefore selects the Marketing Director that has been previously stipulated by the user in the "Gestione Dati Azienda" feature. He can select the Marketing Director clicking on the "Cerca" link; a look-up will open, where the user has the option to search for and select a Marketing Director. The Marketing Director may be selected only if the assembled device is legally registered in a non -EU country.
Assembled Tipo	The list contains the types of assembled devices. They vary based on the choice made in the corresponding "Tipo" field. Therefore, distinct types of system and kits exist.

Assembled Components List Data Field

Field Name	**Description**
Descrizione	Brief description of the component of the assembled device
Nome commerciale e modello	Commercial name given to the component.

Codice attribuito dall' assemblatore (identificativo catalogo)	Indication of product code assigned to component.
Fabbricante/Titolare	Indication of the Manufacturer/title holder of the component
Tipo prodotto	Type of component. The component of an assembled device can be: • Classified Medical Device (DM) • Medical and surgical aids (PMC) • Medicines (SPM) • Other (ALT)
Stato nella base dati	This field is only given value if the component is a DM. Indicates the status of the DM in the database. The status can be changed in the following order: • L: Processing • V: Valid • P: Published

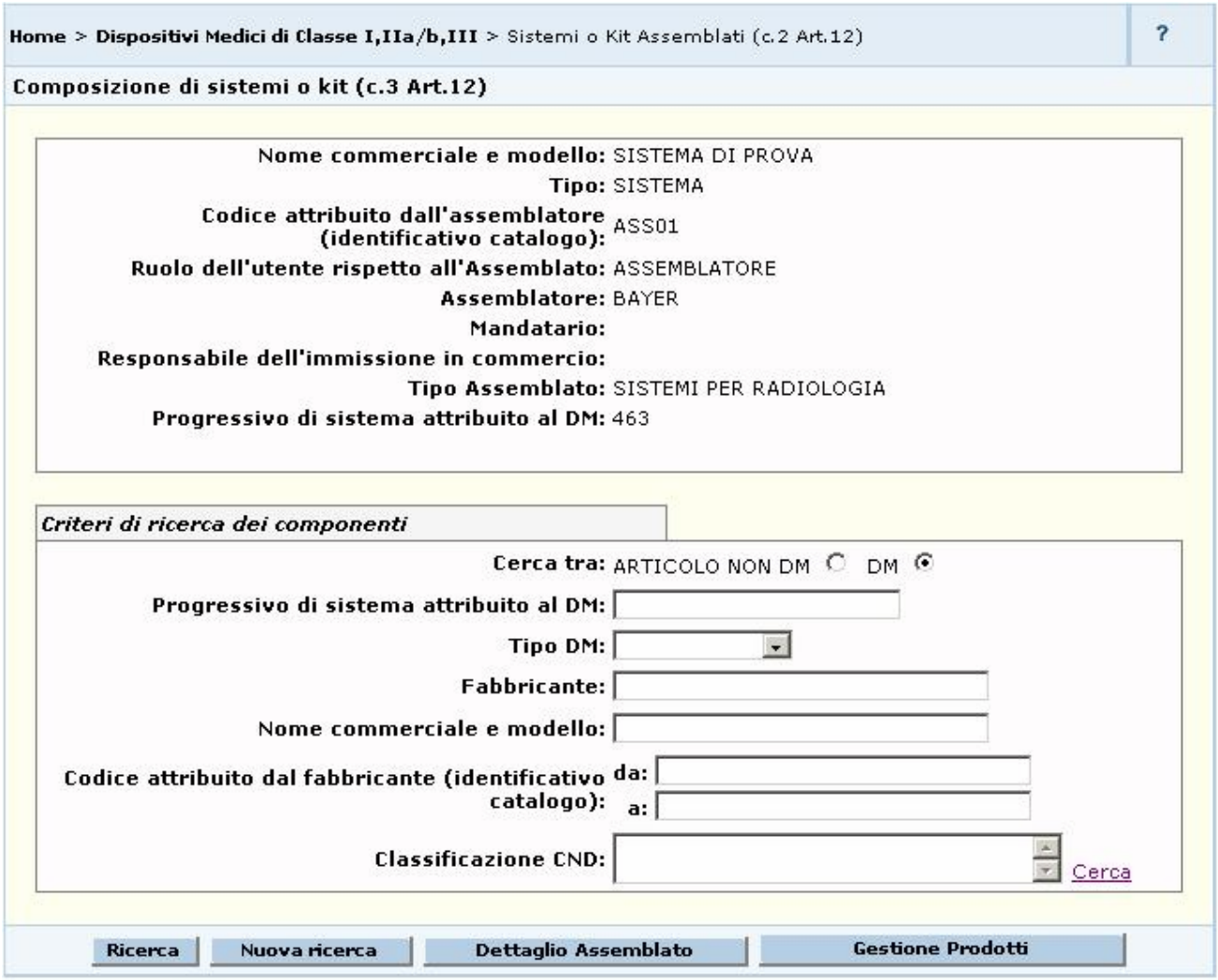
Operations available

Action	**Description**	**Page name**
Aggiungi	Grants access to the search page of the components, in order to add one to a system or kit	RicercaComponenti
Cancella	Allows user to delete the association between selected components and an assembled system or kit	Same
Salva	Saves the operations carried out by the user	Same
Gestione Prodotti	Opens a window where the user has the option to manage (insert, edit, delete and view)Non-DM items; type "Altro"	LookUpRicercaProdotti.

2.3.2.4 RicercaComponenti (DM)

This page allows the user to enter search criteria for the components. The user must select whether he wants to search among DM or Non-DM items. Based on this choice, the page will display differing search criteria. In this paragraph we will examine the case in which the user intends to search among DM.

After having chosen between DM or Non-DM items, the user must enter an additional search margin.
Detailed information concerning the system or kit which is being inserted or edited are displayed.



DM data search Fields

Field Name	Description
Cerca tra	The user must choose if he wants to search among DM list or other products. Different search criteria will be displayed depending on this choice
Progressivo di sistema attribuito al DM	Option to serch a Medical device by its identification number assigned by the system during registration into the database.
Tipo DM	The user can choose between the following types of DM: • Device • System • Kit
Fabbricante	The user can insert the name (or part thereof) of the Manufacturer of the DM

Codice attribuito dal fabbricante (identicativo catalogo) da/a	Option to indicate the range of codes which includes the product code assigned to the DM by the Manufacturer.
Nome commerciale e modello	The DM's name (or beginning of) given by the manufacturer, can be indicated
Classificazione CND	Indicates the national classification of the DM To select a CND classification, click on the "Cerca" link; a look-up will open from which it will be possible to search for a CND classification by code and description

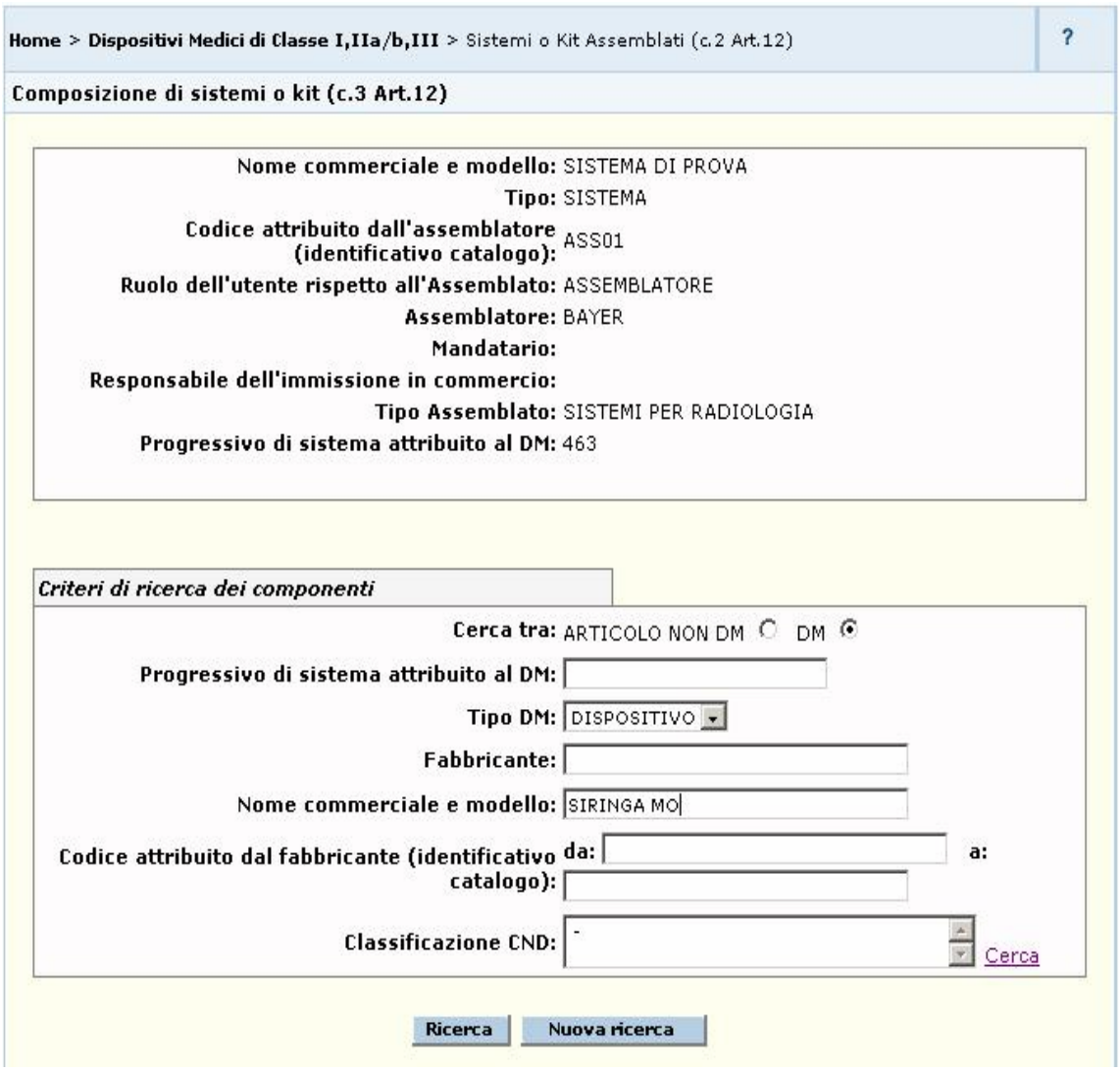
Operations available

Action	**Description**	**Page name**
Ricerca	Runs a search with criteria put in place and displays the DM list that match the same criteria	ListaComponenti
Reset	Clears the search criteria previously put in place	Same
Dettaglio Assemblato	Allows user to return to the data page of the assembled device	DetAssemblatoInsMod.
Gestione Prodotti	Opens a window where the user has the option to manage (insert, edit, delete, view) Non-DM items; type "Altro"	LookUpRicercaProdotti.

2.3.2.5 ListaComponenti (DM)

This page allows the user to view the list of DM (to add as components of the assembled system or kit) coherent with the search criteria put in place.

Detailed information concerning the system or kit which is being inserted or edited are displayed.



Nome commerciale e modello	Codice attribuito dal fabbricante (identificativo catalogo)	Fabbricante	Stato nel repertorio	Tipo DM	Seleziona
SIRINGA MONOUSO	556667	ESAOTE SPA	L	DISPOSITIVO	☐

Pagina 1 di 1

Stato nel repertorio: C=CONSOLIDATO L=IN LAVORAZIONE P=PUBBLICATO V=VALIDATO

Seleziona: Per aggiungere un componente occorre preventivamente cliccare su uno dei quadratini in corrispondenza del componente o dei componenti presenti nella lista.

Aggiungi Componenti | Dettaglio Assemblato | Gestione Prodotti

DM Data Search Fields

Field Name	Description
Cerca tra	The user must choose if he wants to search among DM list or other Non-DM products. Different search criteria will be displayed depending on this choice
Progressivo di sistema	Option to serch a Medical device by its identification

attribuito al DM	number assigned by the system during registration into the database.
Tipo DM	The user can choose between the following types of DM: • Device • System • Kit
Fabbricante	The user can insert the name (or part
Codice attribuito dal fabbricante (identicativo catalogo)	Product code assigned to the DM by the Manufacturer.
Nome commerciale e modello	The DM's name (or beginning of) given by the manufacturer, can be indicated
Classificazione CND	Indicates the national classification of the DM To select a CND classification, click on the "Cerca" link; a look-up will open from which it will be possible to search for a CND classification by code and description

DM Data List

Field Name	**Description**
Nome commerciale e modello	Name of the component as given by Manufacturer.
Codice attribuito dal fabbricante (identicativo catalogo)	Specific code attributed to the DM by the manufacturer
Fabbricante	Manufacturer of the component.
Stato nella base dati	The status of the DM in the database. The status can change in the following order: • L: Processing • V: Valid • P: Published
Tipo DM	There are three types of DM: • Device • System • Kit

Operations available

Action	**Description**	**Page name**
Ricerca	Runs a search with the criteria in place and displays a list of the DM that correspond to the same criteria.	Same
Reset	Clears the search criteria previously	DetAssemblatoInsMod

	entered	
Aggiungi Componente	Allows user to add the components selected to the assembled system or kit	DetAssemblatoInsMod
Dettaglio Assemblato	Allows he user to return to the data page of the assembled device	DetAssemblatoInsMod
Gestione Prodotti	Opens a window where the user has the option to manage (insert ,edit, delete and view)Non-DM items; type “Altro”	LookUpRicercaProdotti.

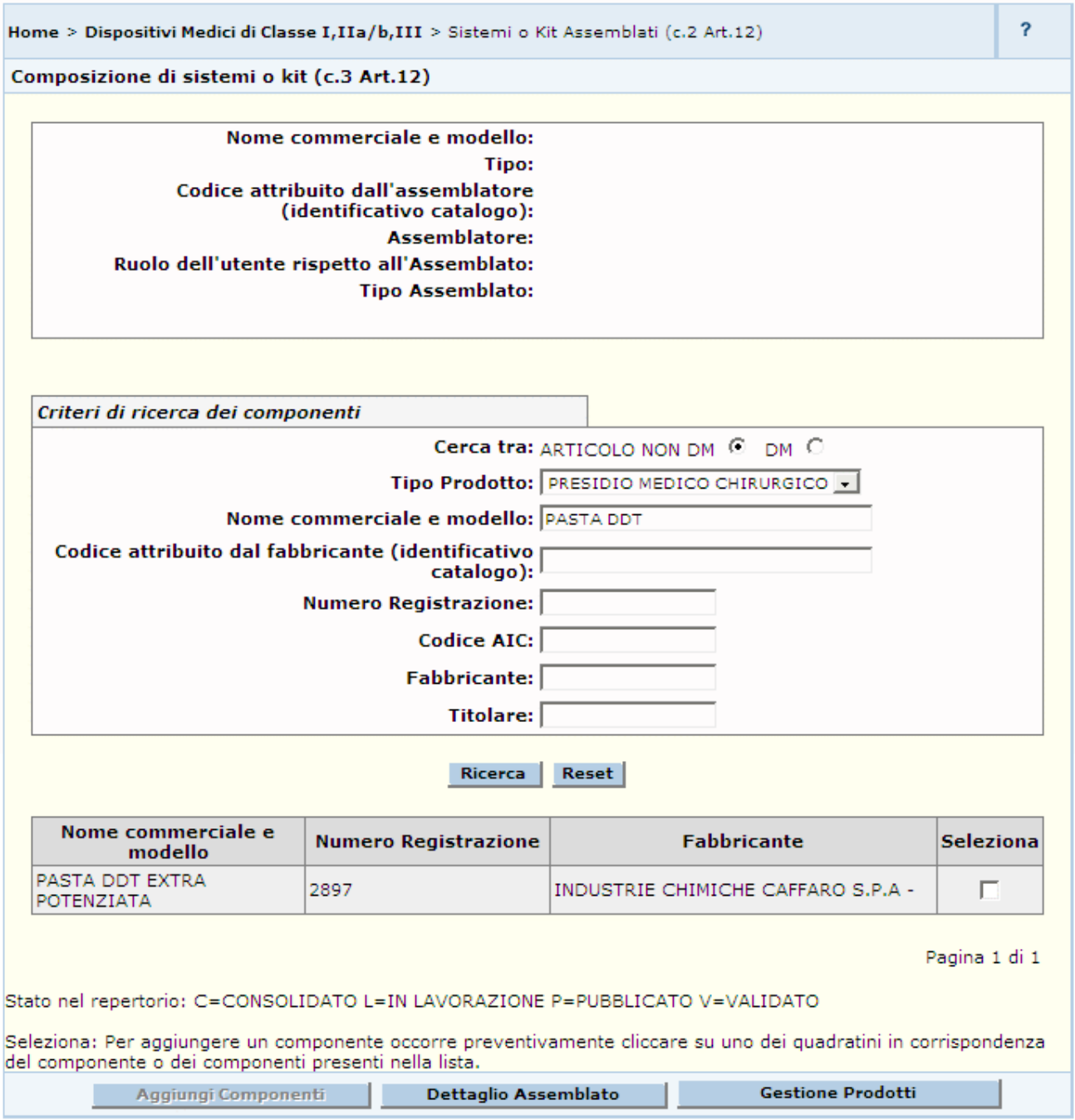
2.3.2.6 RicercaComponenti (Non-DM items)

This page allows search criteria for the components to be put in place. The user must choose whether he wants to search among the DM or non-DM items. Based on this choice, the page will display differing search criteria. In this paragraph, we will examine the case in which the user wishes to search among non-DM items.
The user may associate the following typology:

1. Medical and surgical aids
2. Medicinal products
3. Other

After having decided whether to search among the DM or non-DM items, the user must insert an additional search margin.

Detailed information concerning the system or kit which is being inserted or edited are displayed.



Non-DM Item Data Search Fields

Field Name	Description
Ricerca	The user must choose if he wants to search among DM or other non-DM items. Different search criteria will be displayed depending on this choice
Tipo di Prodotto	The user can choose between the following types of non-DM items: • Surgical and medical aids • Medicinal products • Other

Nome commerciale e modello	The DM's name (or beginning of) given by the manufacturer, can be indicated
Codice attribuito dal fabbricante (identicativo catalogo)	Product code assigned to the DM by the Manufacturer.
Codice AIC	The AIC code refers solely to Medicinal products
Fabbricante	The user can indicate the name (or part thereof) of the Manufacturer (referring to DM that are not stamped, medical and surgical aids and other)
Titolare	The title holder's name (or beginning of), can be indicated (In reference to medicines)

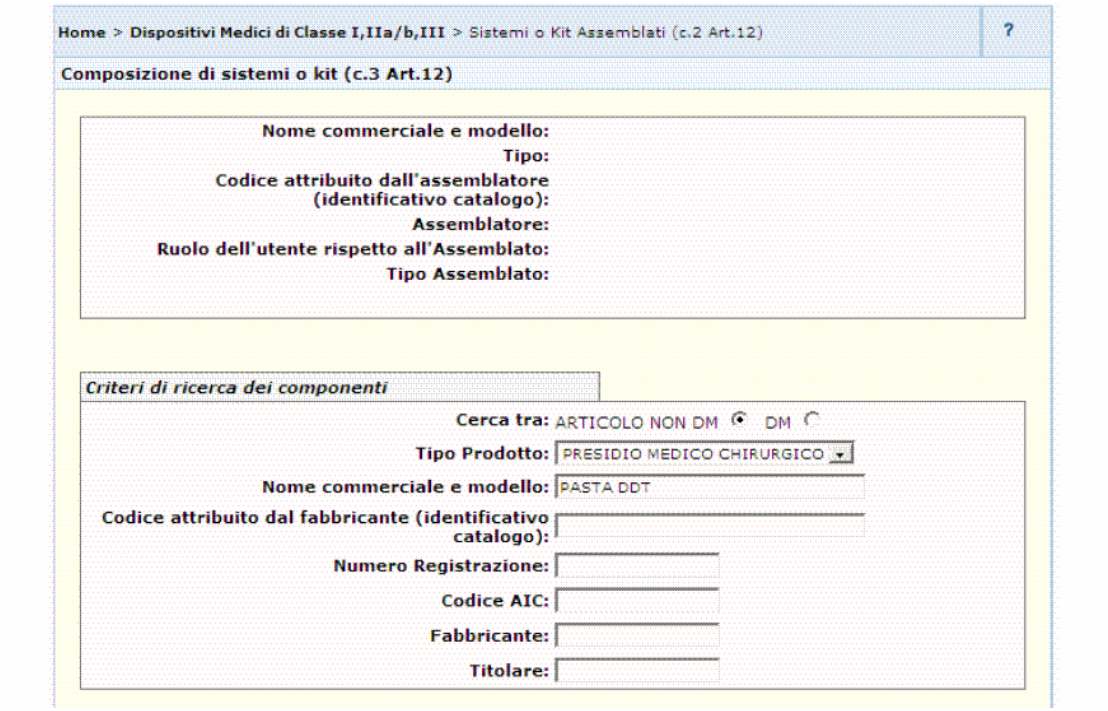
Operations available

Action	**Description**	**Page name**
Ricerca	Runs a search with the criteria in place and displays a list of the non-DM items that correspond to the same criteria.	ListaComponenti
Reset	Clears the search criteria previously entered	Same
Dettaglio Assemblato	Allows the user to return to the data page of the assembled device	DetAssemblatoInsMod
Gestione Prodotti	Opens a window where the user has the option to manage (insert ,edit, delete and view) non-DM items; type "Altro"	LookUpRicercaProdotti.

2.3.2.7 ListaComponenti (DM)

This page allows the user to view the list of non-DM items (to add as components to an assembled system or kit) corresponding to the search criteria in place.

Detailed information concerning the system or kit which is being inserted or edited are displayed.



Non-DM Item Data Search Fields

Field Name	Description
Cerca Tra	The user must choose if he wants to search among DM or other non-DM items. Different search criteria will be displayed depending on this choice
Tipo di Prodotto	The user can choose between the following types of non-DM items: • Surgical and medical aids • Medicinal products • Other
Nome commerciale e modello	The non-DM item's name (or beginning of) given by the manufacturer or title holder, can be indicated

Codice attribuito dal fabbricante (identicativo catalogo)	Product code assigned to the non-DM item by the Manufacturer.
Numero Registrazione	The registration is only in reference to Medical and surgical aids
Codice AIC	The AIC code refers solely to Medicinal products
Fabbricante	The user can indicate the name (or part thereof) of the Manufacturer (referring to DM that are not stamped, medical and surgical aids and other)
Titolare	The Title holder's name (or beginning of), can be indicated (In reference to medicines)

Non-DM Item Data List Search Fields

Field Name	**Description**
Nome commerciale e modello	Name of non-DM item (or beginning of) given by the manufacturer or Title holder.
Codice attribuito dal fabbricante (identicativo catalogo)	Product code assigned by the Manufacturer to the non-DM item; type "Altro".
Numero Registrazione	Registration number (Referring only to Medical and surgical aids)
Codice AIC	AIC code (referring solely to Medicinal products)
Fabbricante	Name of the Manufacturer (of medical and surgical aids and other)
Titolare	Title holder (In reference to medicines)

Operations available

Action	**Description**	**Page name**
Ricerca	Runs a search with the criteria in place and displays a list of the non-DM items that correspond to the same criteria.	Same
Reset	Clears the search criteria previously entered	Same
Aggiungi Componente	Allows user to add the components selected to the assembled system or kit	DetAssemblatoInsMod
Dettaglio Assemblato	Allows the user to return to the data page of the assembled device	DetAssemblatoInsMod
Gestione Prodotti	Opens a window where the user has the option to manage (insert ,edit, delete and view) non-DM items; type "Altro"	LookUpRicercaProdotti.

2.3.2.8 DetAssemblatoVis

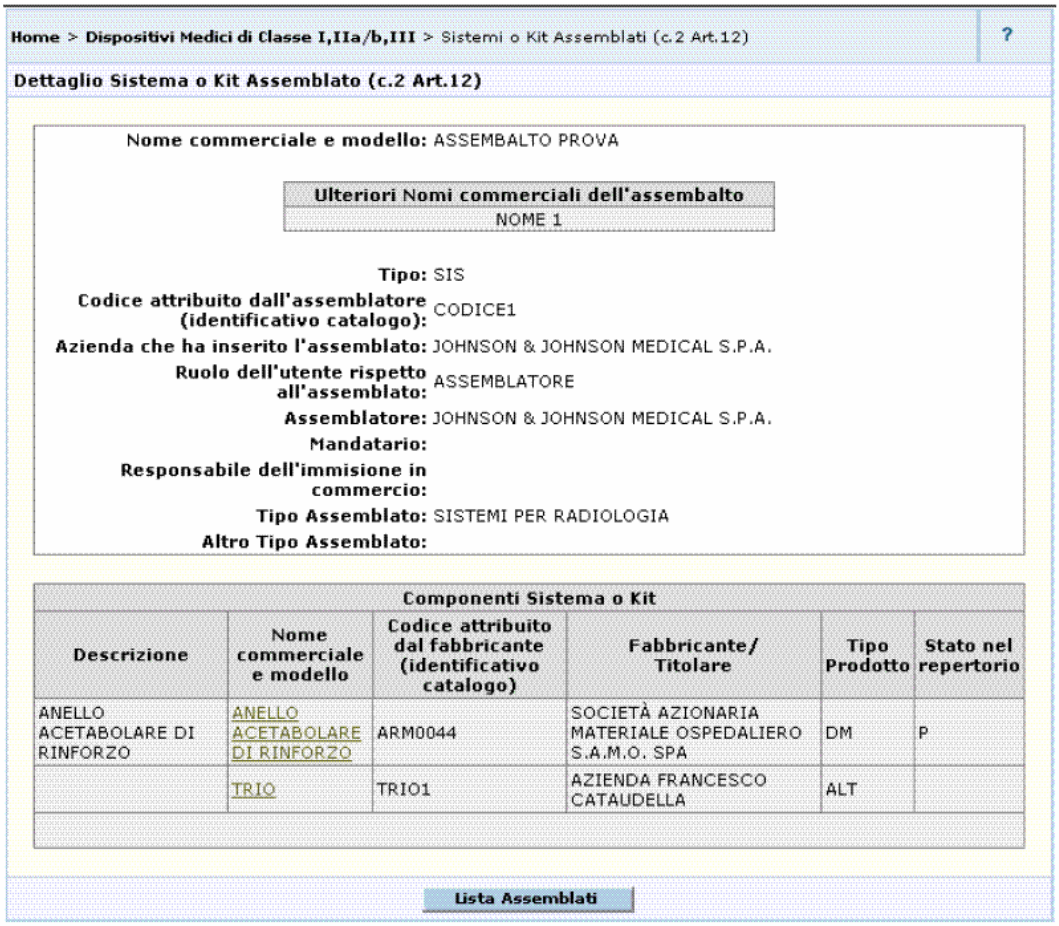
This page allows the user to view information regarding an assembled system or kit in read-only mode.

The detailed information of an assembled device can be viewed by the following types of users:

1. Fab/Man/RIC/ASD users, as regards their own inserted assemble devices
2. DGFDM users, as regards all assembled devices that are have the “validato” or “publicato” status
3. REGIONE and AZIENDESANITARIEDM users

In order to view the data of a DM, both types of user must proceed as follows:

1. Run the search for the assembled device (by clicking on “Gestione Assemblati” in the menu, insert the search criteria by clicking on the “Ricerca” button)
2. Select the desired device and click on the “Visualizza” button to access the data page.



Assembled Device Data Fields

Field Name	**Description**
Nome commerciale e modello	Name of the system or kit the manufacturer has given
Tipo	Type of assembled device. The device can be one of two types • System • Kit
Codice attribuito dall' assemblatore (identificativo catalogo)	Indication of product code assigned to the system or kit by the Assembler.
Assemblatore	Name of the assembler of the assembled system or kit.
Mandatario	Name of Mandate Holder of the assembled system or kit.
Responsabile dell'immissione in commercio	Name of Marketing Director of the assembled system or kit.
Ruolo dell'utente rispetto all'assemblato	Indicates the role carried out by the user with respect to the assembled device. The user can adopt the following roles: • Assembler • Manufacturer • Mandate Holder • Marketing Director

	• Other individual delegated by the Manufacturer.
Tipo Assemblato	Indication of the type of assembled devices.

Assembled Components List Data Fields

Field Name	**Description**
Descrizione	Brief description of the component of the assembled device
Nome commerciale e modello	Commercial name given to the component.
Codice attribuito dall' assemblatore (identificativo catalogo)	Indication of product code assigned to component.
Fabbricante/Titolare	Name of the Manufacturer/title holder of the component
Tipo prodotto	Type of component. The component of an assembled device can be: • Classified Medical Device (DM) • Medical and surgical aids (PMC) • Medicines (SPM) • Other (ALT)
Stato nella base dati	This field is only given value if the component is a DM. Indicates the status of the DM in the database. The status can change in the following order: • L: Processing • V: Valid • P: Published

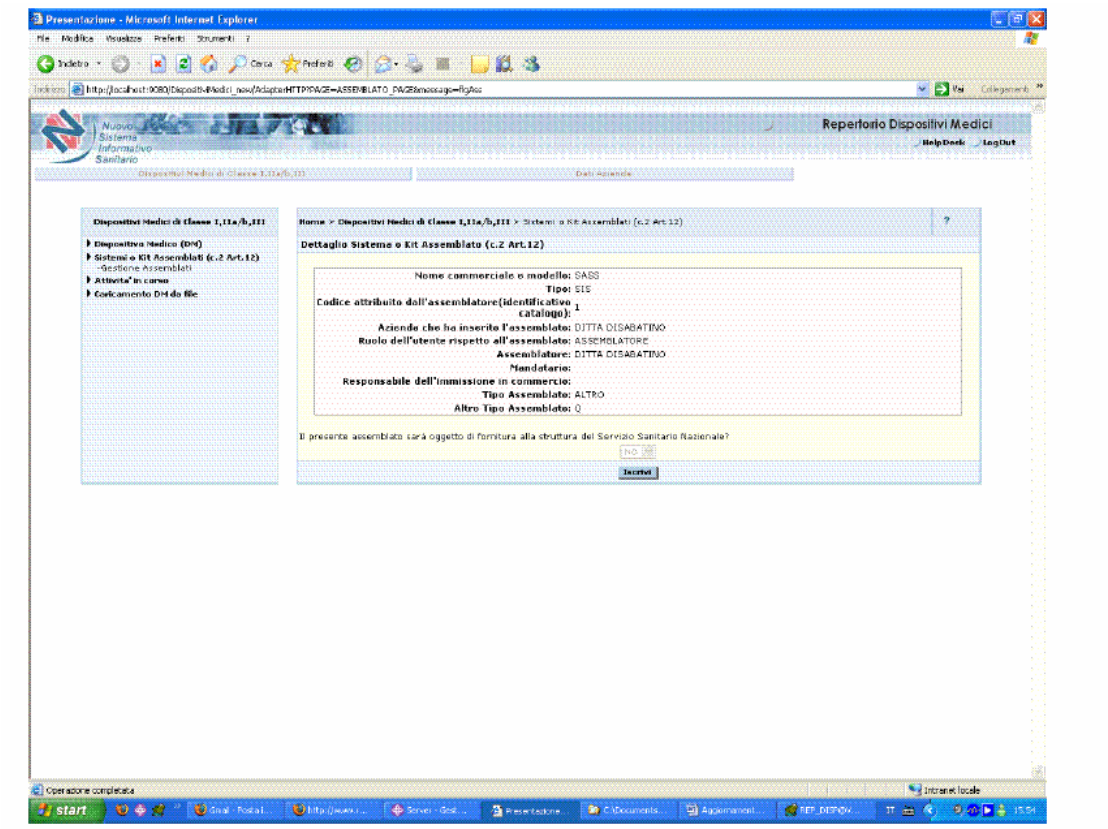
Operations available

Action	**Description**	**Page name**
List of assembled devices	Allows the user to return to the list of the assembled devices	ListaAssemblati

2.3.2.9 Registration on the index

To register an assembled device that contains at least one DM the user must proceed as follows:

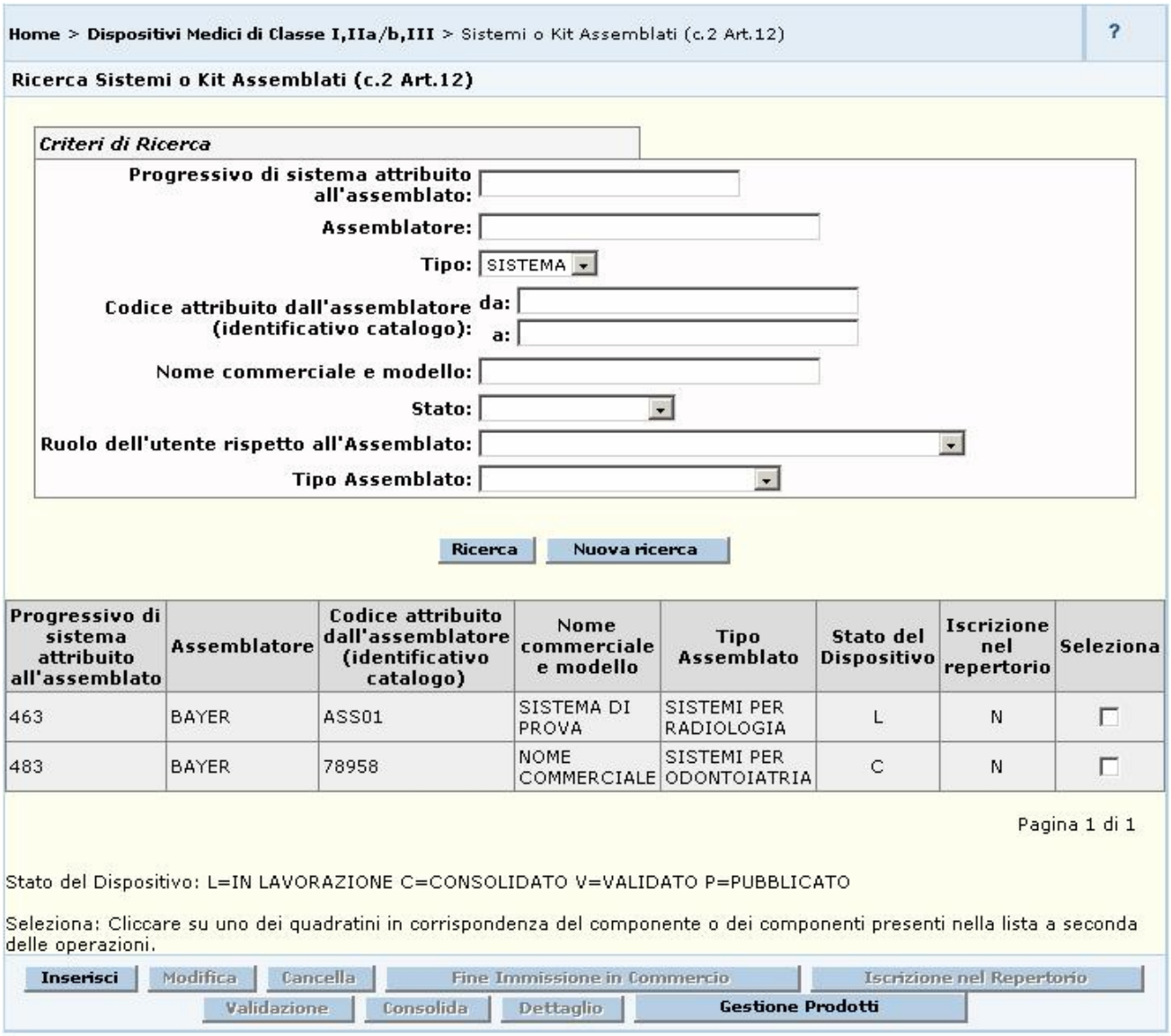
1. Run a search for DM (by clicking on "Dispositivo Medico (DM)" in the menu, insert the search criteria and then click on the "Ricerca" button);
2. Select an assembled device found in the "Validato" or "Pubblicato" stage;
3. Click on the "Inscrizione nel repertorio" button.



The user must then state that he wishes to make the assembled device available to the S.S.N. by entering “Si”, the system alerts the user that the choice made cannot be changed and checks that all of the components have been registered on the index. If the check results positive, the assembled device is then registered on the index, otherwise a message stating the opposite is sent to the user.

2.3.2.10 Off-Market Date

This page allows the user o insert the off-market date in reference to an assembled system or kit in the “Validato” or “Pubblicato” stage.



Assembled Device Data Fields

Field Name	**Description**
Progressivo di sistema attribuito all'assemblato	Identification number assigned to the Assempbed device by the system during registration into the database.
Nome commerciale e modello	Name of the system or kit as given by the manufacturer.
Tipo	Type of assembled device. The device can be one of two types • System • Kit
Codice attribuito dall' assemblatore (identificativo catalogo)	Indication of product code assigned to the system or kit by the Assembler.

Assemblatore	Name of the assembler of the assembled system or kit.
Stato	Option to serch an Assembled device by its current status into the system (“In lavorazione”, “Consolidato”, “Validato”, “Pubblicato”).
Ruolo dell’utente rispetto all’assemblato	Indicates the role carried out by the user with respect to the assembled device. The user can adopt the following roles: • Assembler • Mandate Holder • Marketing Director • Other individual delegated by the Manufacturer.
Tipo Assemblato	Indication of the type of assembled device.

Assembled Components List Data Fields

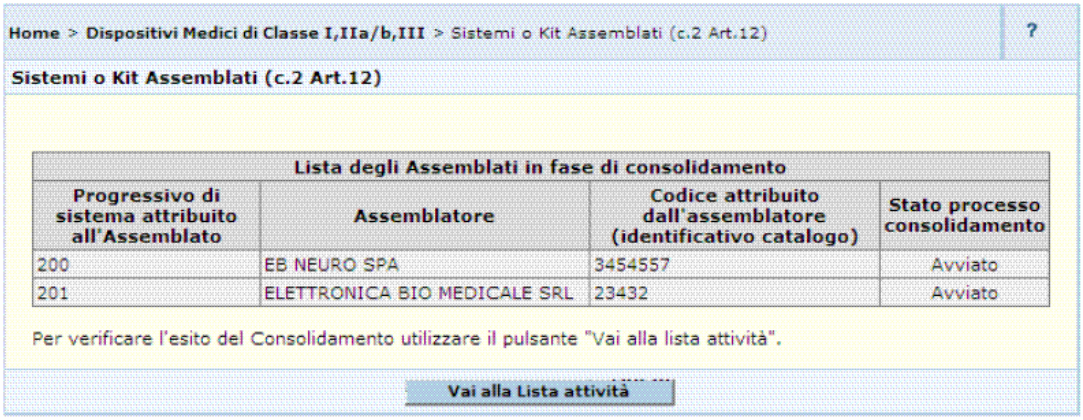
Field Name	**Description**
Nome commerciale e modello	Name of the component.
Fabbricante/Titolare	Indicates the name of the Manufacturer/title holder of the component
Tipo prodotto	Type of component. The component of an assembled device can be: • DM • Medical and surgical aids (PMC) • Medicines (SPM) • Other (ALT)

Operations available

Action	**Description**	**Page name**
Salva	Saves the information entered	ListaAssemblati

2.3.2.11 Assembled Device Approval Page

This page allows the user to view the list of assembled devices in the approval phase. The activation of approval corresponding to one or more assembled devices involves the activation of consistency ad coherency tests on the information entered. Should errors arise in this phase, these will be visible on the activity list feature on the menu option “Attività in corso”. Should the tests result positive, the device’s status is updated to “Consolidato” ; a preliminary stage before the validation, while awaiting the electronic signature.



Assembled Devices in the approval phase List Data Fields

Field Name	Description
Progressivo attribuito all'Assemblato	Product code assigned to each assembled device
Assemblatore	Name of the assembler
Codice attribuito dall' assemblatore (identificativo catalogo)	Indication of product code assigned to the system or kit by the Assembler.
Stato processo validazione	The status of the process. It can change status in the following order: • Initiated • Not Initiated

Operations available

Action	Description	Page Name
Vai alla Lista attività	Allows user to return to the activity list	listaAttività

2.3.2.12 Assembled Device Signature Page

This page allows user, who has inserted the specific assembled device, to digitally sign, in order to validate that same device.
The user must be in possession of a Smart Card in order to sign digitally.

To validate an assembled device, the user must proceed as follows:

1. Run a search of assembled devices (from the "Gestione Assemblati" option on the menu)
2. Select an assembled device marked "in lavorazione" and click on the "Validazione" button
3. Click the "Firma" button
4. Insert the PIN code in the space provided

Before digitally signing, the user must be sure to read the text displayed on the signature page which is laid out as follows:

"Il sottoscritto… (name and surname of user connected), per conto di… (name of assembler) convalida … (commercial name and type of assembled device) con identicativo catologo…in data … (today's date)"

In order for the validation to be successful and the request for release to arrive at the DGFDM department, the valid assembled device must have the following:

1. All required general data of the assembled device (Assembler, Type, code assigned by the assembler, Commercial name and assembled device type).
2. The indication of at least two components, one of which must be a DM.
3. Publication of all components of the assembled device.

Operations available

Action	Description	Page Name
Firma	Allows user to validate an assembled device after having entered the PIN in the space provided	PaginaSintesiAssemblato

2.3.2.13 Assembled Device Summary Page

This page displays the principle information of the assembled device awaiting validation, in read-only format

Assembled Devices in the Validation phase List Data Fields

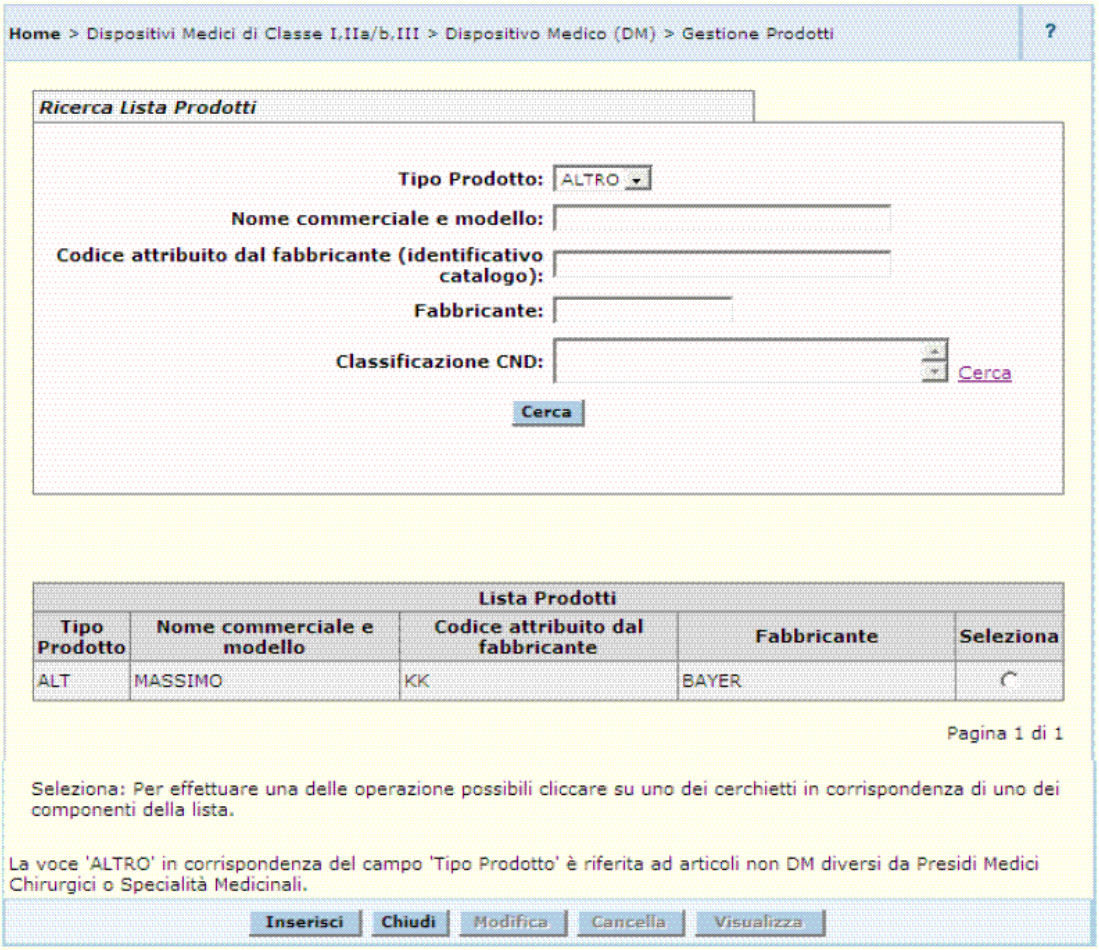
Field Name	Description
Assemblatore	Name of the assembler
Codice attribuito dall' assemblatore (identificativo catalogo)	Indication of product code assigned to the system or kit by the Assembler.
Nome commerciale e modello	Name of the system or kit assigned by the assembler
Stato processo validazione	The status of the process. It can change status in the following order: • Initiated • Not Initiated

Operations available

Action	Description	Page Name
ListaAssemblati	Allows user to return to the list of assembled devices, with the status of the device valid and updated	listaAssemblati

2.3.2.14 LookUpRicarcaProdotti

This page allows the user to put search criteria in place in order to view the list of non-DM products; Type “Altro”.


Home > Dispositivi Medici di Classe I,IIa/b,III > Dispositivo Medico (DM) > Gestione Prodotti
?
Ricerca Lista Prodotti
Tipo Prodotto: ALTRO
Nome commerciale e modello:
Codice attribuito dal fabbricante (identificativo catalogo):
Fabbricante:
Classificazione CND:
Cerca
Cerca
Lista Prodotti
Tipo Prodotto
Nome commerciale e modello
Codice attribuito dal fabbricante
Fabbricante
Seleziona
ALT
MASSIMO
KK
BAYER
Pagina 1 di 1
Seleziona: Per effettuare una delle operazione possibili cliccare su uno dei cerchietti in corrispondenza di uno dei componenti della lista.
La voce 'ALTRO' in corrispondenza del campo 'Tipo Prodotto' è riferita ad articoli non DM diversi da Presidi Medici Chirurgici o Specialità Medicinali.
Inserisci
Chiudi
Modifica
Cancella
Visualizza

Detail Fields

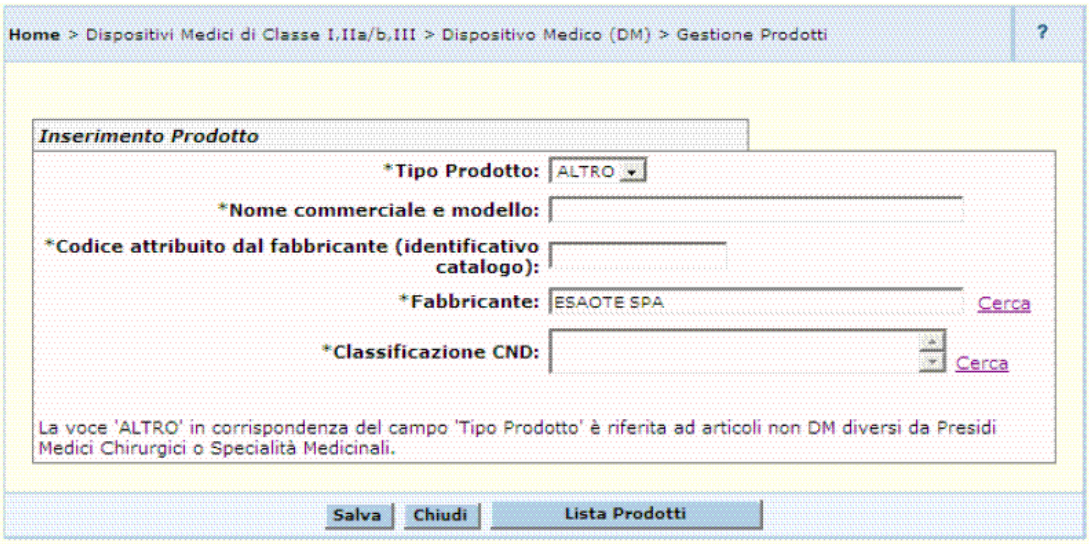
Field Name	Description
Tipo prodotto	The product type has already been inserted as a non-DM product; type “Altro”
Nome commerciale e modello	Option to specify the commercial name (or beginning) of the product
Codice attribuito dall’ assemblatore (identificativo catalogo)	The product code assigned to the product can be specified.
Fabbricante	Option to specify the name (or the beginning) of the Manufacturer.

Operations available

Action	Description	Page name
Ricerca	Runs a search with criteria entered and displays the list of products that match that criteria.	Same
Chiudi	Closes the non-DM product, management window	ListaAssemblati
Inserimento	Displays the insertion page of a non-DM product; type “Altro”	LookUpArtDatiGen
Modifica	Displays the data page of the non-DM product selected from the list (in read-only format)	LookUpArtDatiGen
Visualizza	Displays the data page of the non-DM product selected from the list (in read-only format)	LookUpArtDatiGen
Cancella	Deletes the non-DM product selected from the list.	Same

2.3.2.15 LookUpGestioneProdotti

This page allows the user to insert/edit the information regarding the non-DM products; type “Altro”



Detail Fields

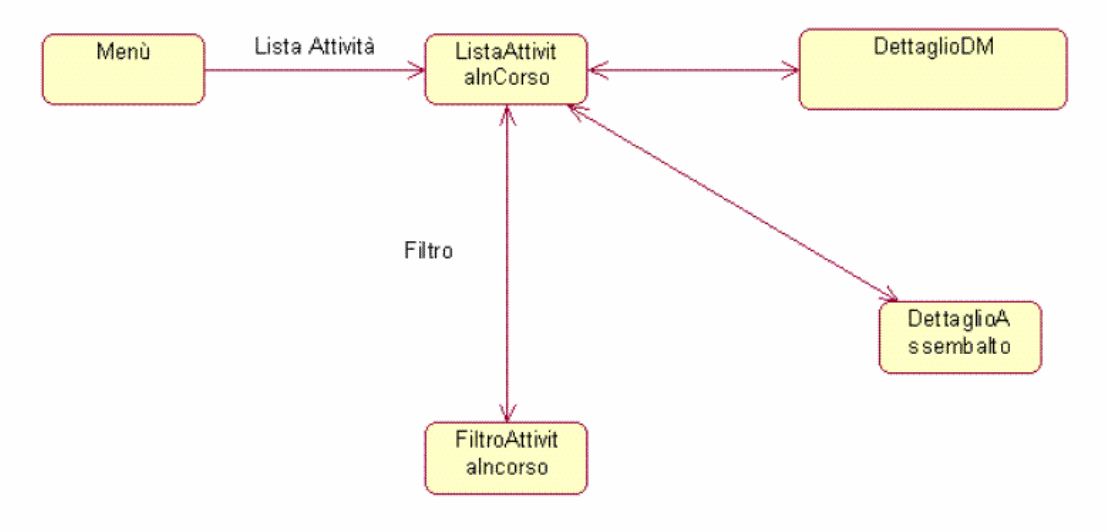
Field Name	Description
Tipo prodotto	• The product type has already been inserted as a non-DM product; type “Altro”
Nome commerciale e modello	• Name assigned to the product by the Manufacturer.
Codice attribuito dall’ assemblatore (identificativo catalogo)	Product code assigned to the product by the manufacturer.
Fabbricante	Indication of the Manufacturer of the product.
Classificazione CND	

Operations available

Action	Description	Page name
Salva	Saves the information entered by the user	Same
Chiudi	Closes the product management window	ListaAssemblati
Lista Prodotti	Allows the user to return to the product list, without saving the information entered.	LookUpProdRic

2.3.3 Menu option “Attività in corso” (Fab/Man/RIC/ASD)”

Screen flowchart:

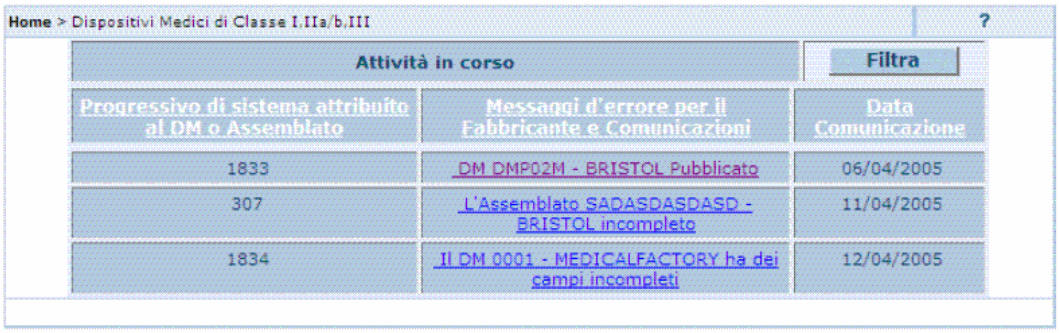


2.3.3.1 ListaAttivitaInCorso (Fab/Man/RIC/ASD)

In order to gain access to the page containing the list of activities in progress, the user must click on the “Lista Attività” menu option.
This page allows the (Fab/Man/RIC/ASD) user to view the activity list in progress, referring to DM am assembled systems or kits (Para.2 Art.12) that have been validated by the respective user.
The user may receive the following messages in reference to each DM validated:

- Successful publication by the DGFDM department.
- Modification request from the DGFDM department
- Modification request due to failure to pass the following automatic tests:
  1. Missing required general data and attached documentation for the DM.
  2. Missing required data for the assembled systems or kits
  3. Failure to indicate other DM required for its function, if in the general data of the DM, in correspondence with the data sheet “Legami con altri DM” it was marked “Si”.
  4. Failure to indicate at least two systems and kits components, of which one had to be a Non-CE marked DM, in accordance with Para.2 Art.12.
  5. Failure to indicate at least two assembled system and kit components, of which one had to be a DM, in accordance with Para.3 Art.12.
  6. Failure to publish all systems and kit components, in accordance with Para.2 Art.12.
  7. Failure to publish all system and kit components, in accordance with Para.3 Art.12.

Clicking on the link corresponding with the “Comunicazione e messaggi d’errore” column, displays the data page containing the principle data of the activity in progress selected.



Detail Fields

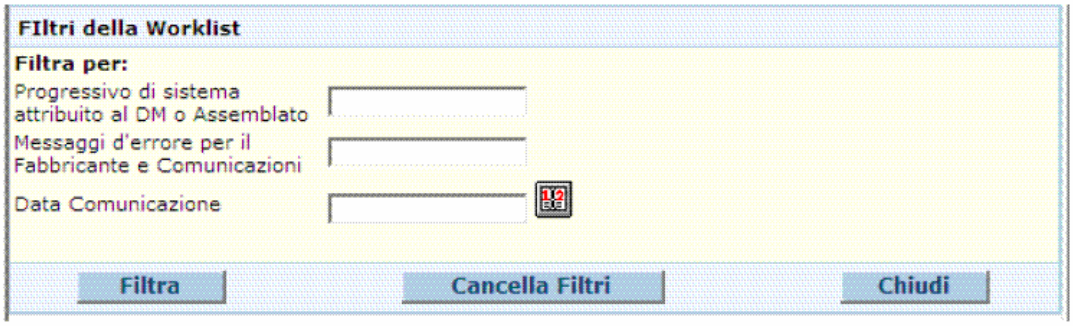
Field Name	Description
Progressivo di sistema attribuito al DM o Assemblato	Consecutive System number of DM or Assembled device
Messaggi d'errore per il Fabbricante e Comunicazione	Indicates the type of communication. There can be three types of communication regarding a validated DM or assembled device: • Successful publication by the DGFDM department. • Modification request from the DGFDM department • Modification request due to failure to pass the automatic tests in the system.
Data Comunicazione	Indicates the data where the activity is assigned to the DGFDM department

Operations available

Action	Description	Page name
Filtra	Opens a window from where the user has the option to filter the activity in progress list based on search criteria inserted.	FiltroAttivitaIncorso

2.3.3.2 FiltroAttivitaIncorso(Feb/Man/RIC/ASD)

This page is displayed in look-up format and allows the user to filter the activity in progress list based on search criteria put in place.



Detail Fields

Field Name	Description
Progressivo di sistema attribuito al DM o Assemblato	Consecutive System number of DM or Assembled device
Messaggi d'errore per il Fabbricante e Comunicazione	Indicates the type of communication. There can be three types of communication regarding a validated DM or assembled device: • Successful publication by the DGFDM department. • Modification request from the DGFDM department • Modification request due to failure to pass the automatic tests in the system.
Data Comunicazione	Indicates the data where the activity is assigned to the DGFDM department

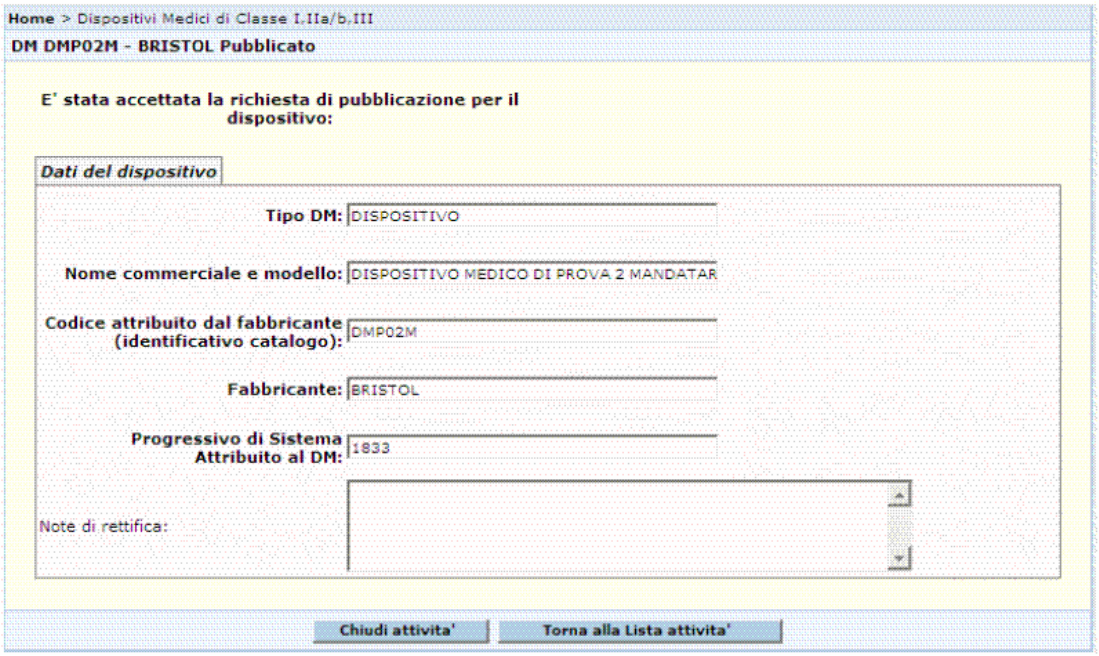
Operations available

Action	Description	Page name
Filtra	Runs a search of the activities in progress based on search criteria inserted.	ListaAttivitaIncorso
Cancella filtro	Clears the search criteria previously put in place	Same
Chiudi	Closes the search margin window, without running the search.	ListaAttivitaIncorso

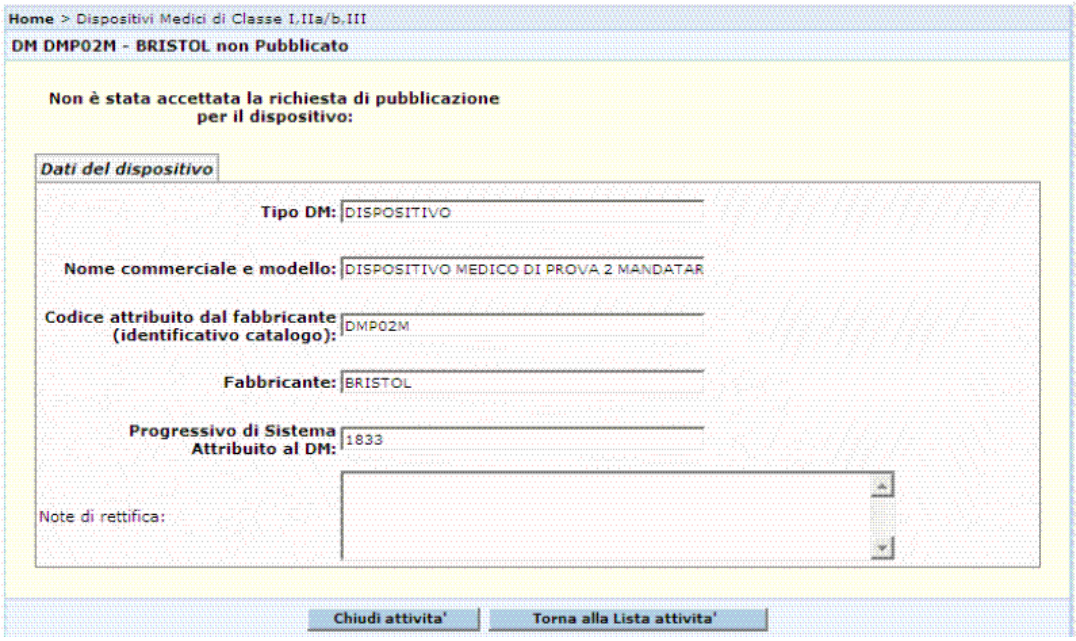
2.3.3.3 DettaglioDM (Fab/Man/RIC/ASD)

This page allows the user to view the principle information regarding the activity in progress resulting in validation/publication.
There are three possible types of communication for a validated DM:

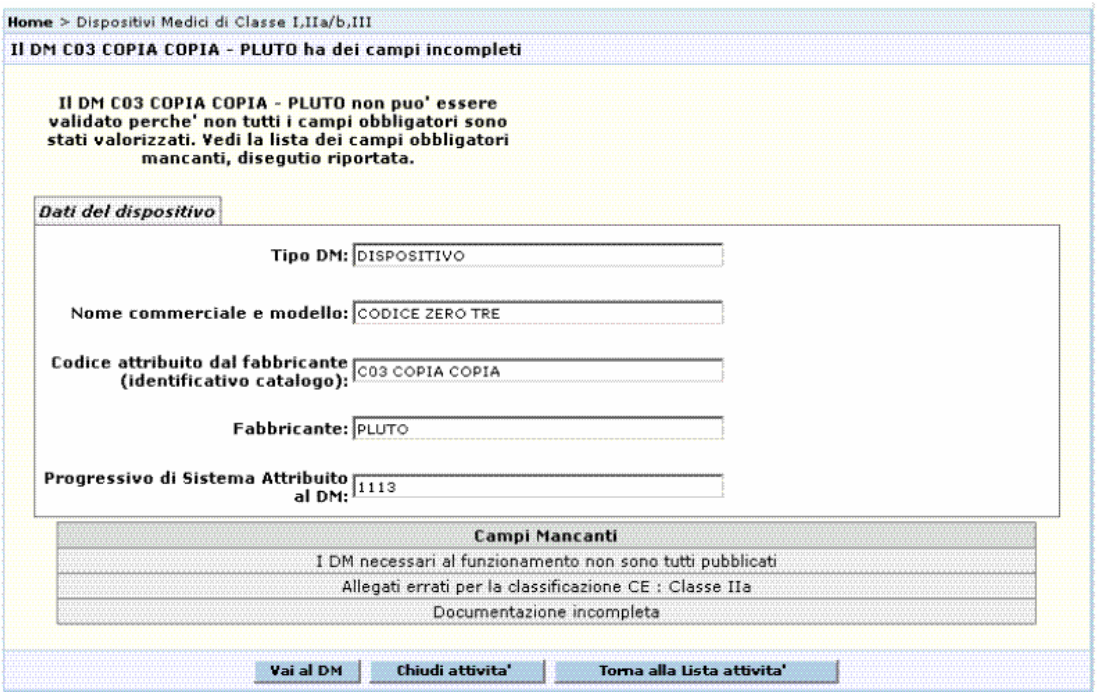
1. Successful publication in the DGFDM department. In this case at the top of the page the phrase "E' stata accettata la richiesta di pubblicazione per la dispositivo…" will appear and then the principle data of the DM will be synthesised.



2. Modification request from the DGFDM department. In this case at the top of the page the phrase “Non e’ stata accettata la richiesta di pubblicazione per la dispositivo…” will appear and then the principle data of the DM will be synthesised.



3. Modification request due to failure to pass the automatic tests in the system. In this case the list of errors which determined the failure to pass the automatic tests in the system, is displayed with the principle data of the DM.



Detail Fields

Field Name	Description
Tipo DM	Indication of the type of classified Medical Device. The following types of DM exist: - Device - System - Kit
Nome commerciale e modello	Denomination of the DM, as assigned by the Manufacturer
Codice attribuito dal fabbricante (identicativo catalogo)	Specific code attributed to the DM by the manufacturer.
Fabbricante	Name of the Manufacturer of the DM
Progressivo di sistema attributo al DM	Consecutive number of DM device by the system
Note per la rettifica	Indication of the reasons that made the DGFDM reject the request for publication of the DM
Campi mancanti	The list of errors that caused the DM to fail the automatic tests of the system for the validation of the DM.

Operations available

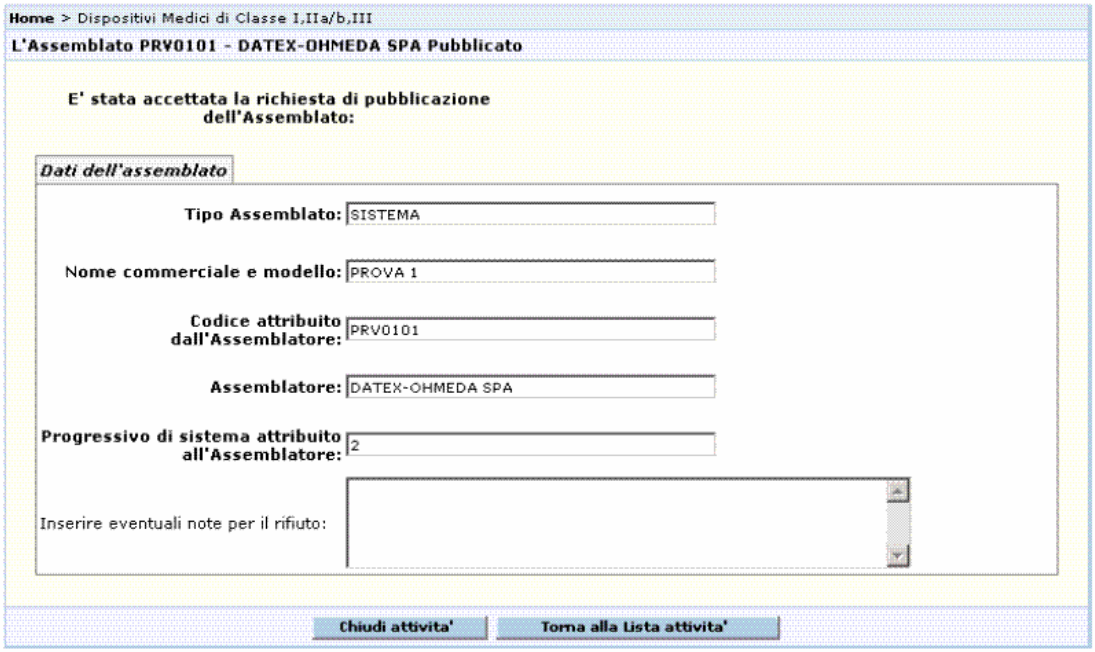
Action	Description	Page name
Vai al DM	Grants access to the general data page of the DM	PaginaDatiGenerali
Chiudi Attività	Allows the user to return to the activities in progress list, eliminating the activity previously selected	ListaAttivitaIncorso
Torna alla lista attività	Allows the user to return to the list of activities in progress	ListaAttivitaIncorso

2.3.3.4 DettaglioAssemblato(Fab/Man/RIC/ASD)

This page allows the user to view the principle data of the activity in progress resulting in validation/publication.

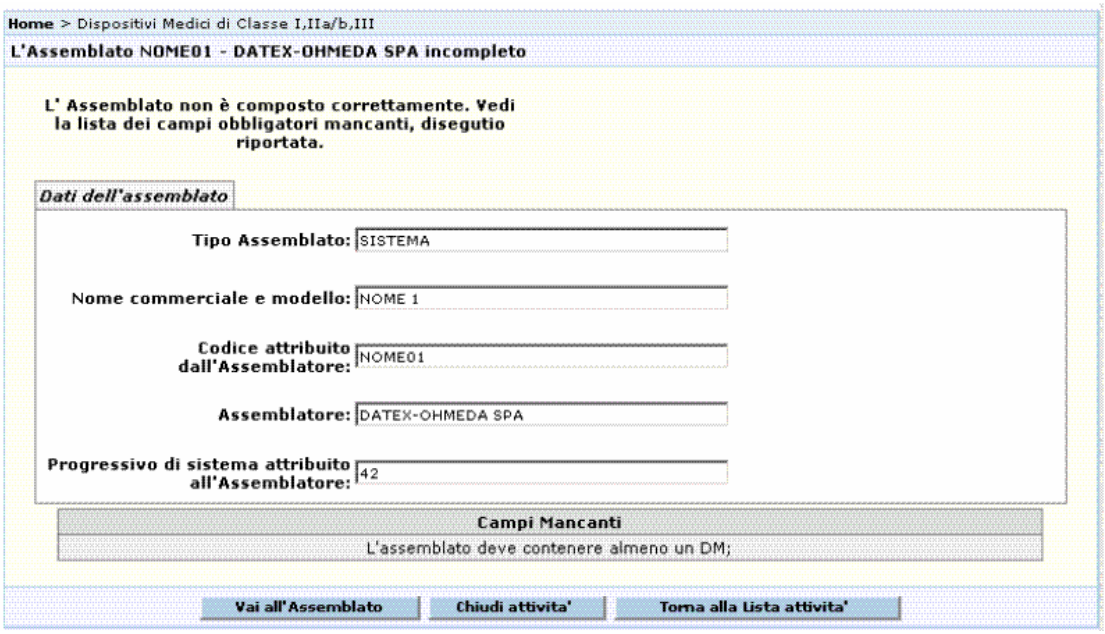
There are three possible types of communication for a validated assembled device.

1. Successful publication in the DGFDM department. In this case at the top of the page the phrase “E’ stata accettata la richiesta di pubblicazione dell’assemblato…” will appear and then the principle data of the assembled device will be synthesised.



2. Modification request from the DGFDM department. In this case at the top of the page the phrase “Non e’ stata accettata la richiesta di pubblicazione dell’assemblato …” will appear and then the principle data of the assembled device will be synthesised.

3. Modification request due to failure to pass the automatic tests in the system. In this case the list of errors which determined the failure to pass the automatic tests in the system, is displayed with the principle data of the assembled device.



Detail Fields

Field Name	Description
Tipo Assemblato	Type of Assembled Device. The following types of Assembled device exist: • System • Kit
Nome commerciale e modello	Denomination of the system or kit, as assigned by the Assembler
Codice attribuito dall' assemblatore (identificativo catalogo)	Specific code attributed to the Assembled system or kit by the Assembler.
Assemblatore	Name of the Assembler of the Assembled system or kit
Progressivo di sistema attribuito all'assemblato	Consecutive number of Assembled device by the system
Note per la rettifica	Indication of the reasons that made the DGFDM reject the request for publication of the Assembled Device
Campi mancanti	The list of errors that caused the Assembled Device to fail the automatic tests of the system for the validation of the Assembled Device.

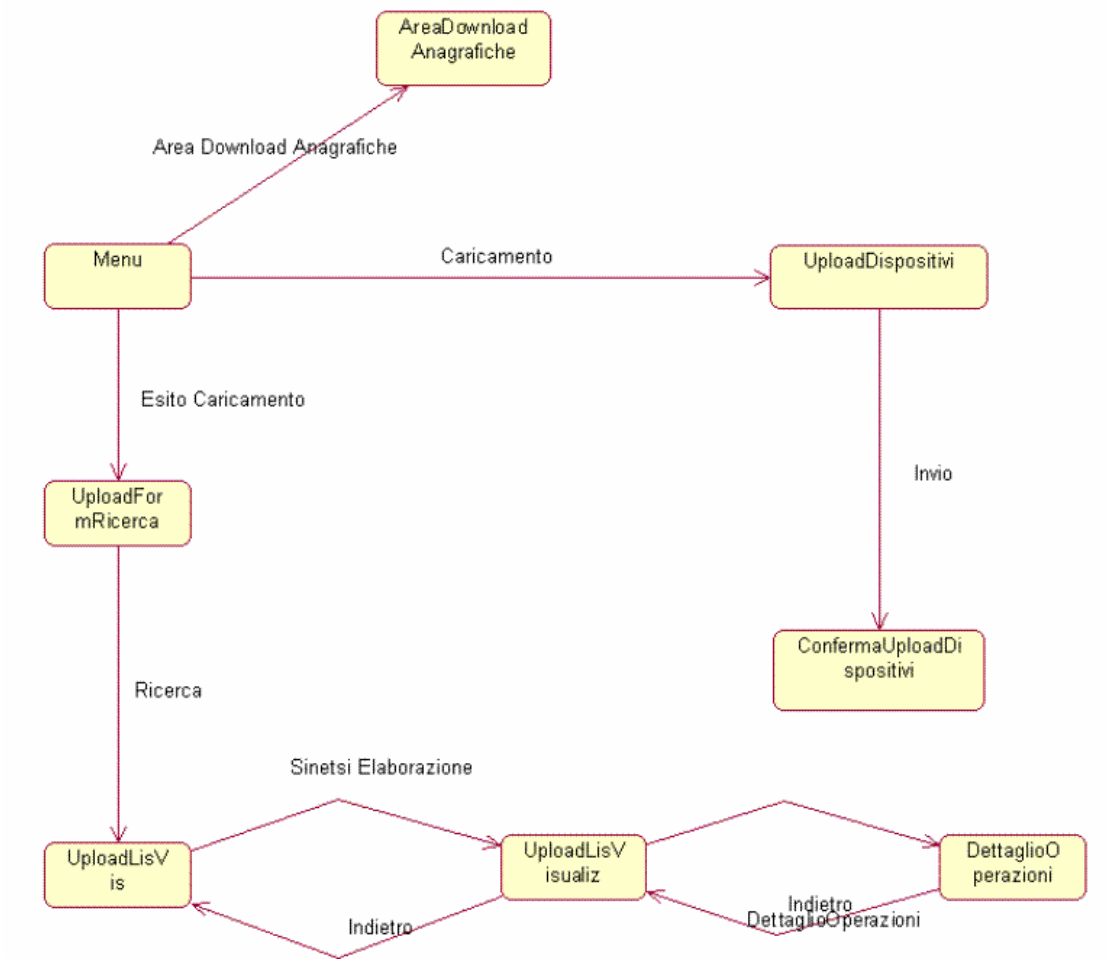
Operations available

Action	Description	Page name
Vai all'assemblato	Grants access to the general data page of the Assembled device	DetAssemblatoIndMod
Chiudi Attività	Allows the user to return to the activities in progress list, eliminating the activity previously selected	ListaAttivitaIncorso

Torna alla lista attività	Allows the user to return to the list of activities in progress	ListaAttivitaIncorso

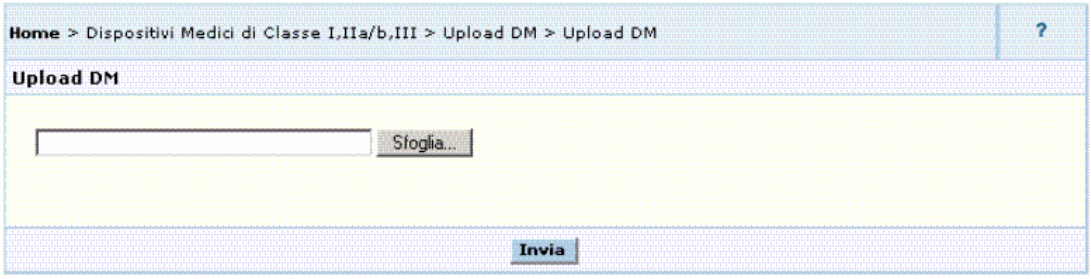
2.3.4 Menu option “Caricamento DM da file”

Screen flowchart:



2.3.4.1 UploadDispositivi

This page allows a Fab/Man/RIC/ASD user to attach a text or xml file containing data regarding their DM.
Such a file must comply with the format previously set out, and has to be programmed by an automatic procedure which will upload the data of the DM within the database.



Detail Fields

Field Name	Description
Upload DM	Having clicked on the "Sfoglia" button, the user must select a text or xml file containing data on the DM from his own file System, according to the record previously indicated.

Operations available

Action	Description	Page name
Invio	Allows the user to upload text or xml file selected	ConfermaUploadDispositivi

2.3.4.2 ConfermaUploadDispositivi

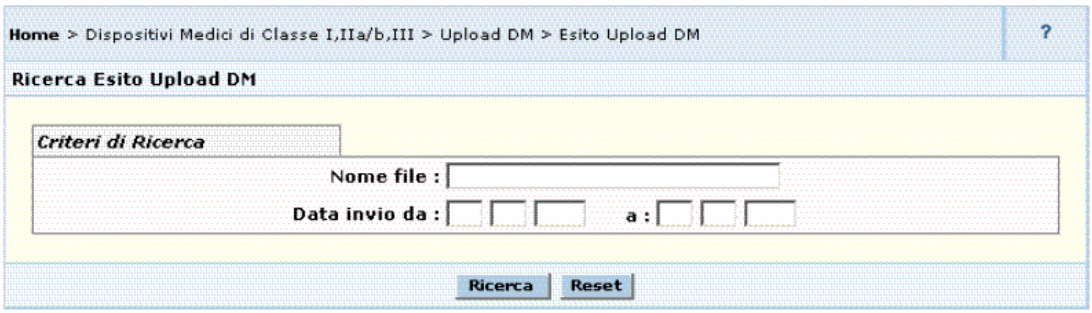
This page displays a message with the result of the upload (carried out by the Fab/Man/RIC/ASD user) from the file containing data regarding their DM.

Operations available

Action	Description	Page name
Ok	Allows the user to return to the page that where they can upload.	UploadDispositivi

2.3.4.3 UploadFormRicerca

This page allows the Fab/Man/RIC/ASD user to insert search criteria in order to view the list of files attached by the user and containing data regarding their DM.



Detail Fields

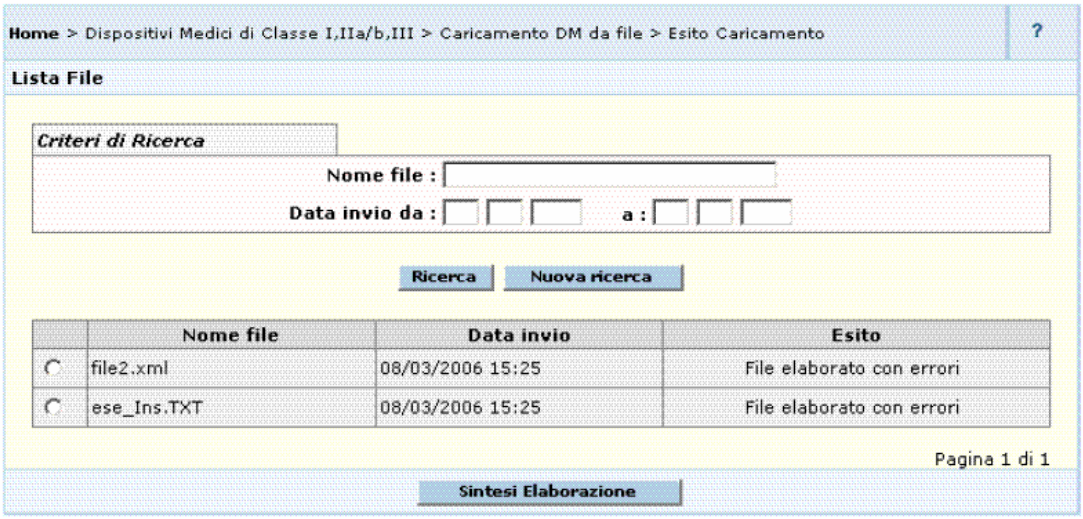
Field Name	Description
Nome File	The name of the file attached by the user, containing the DM's data
Data invio da/a	The date range the user uploaded the file

Operations available

Action	Description	Page name
Ricerca	Runs the search with criteria in place and displays the list of files attached by the user	UploadListaFile.
Reset	Clears the search criteria previously put in place	Same

2.3.4.4 UploadListaFile

This page allows the Fab/Man/RIC/ASD user to view the result of the loading procedure of each file sent.



Detail Fields

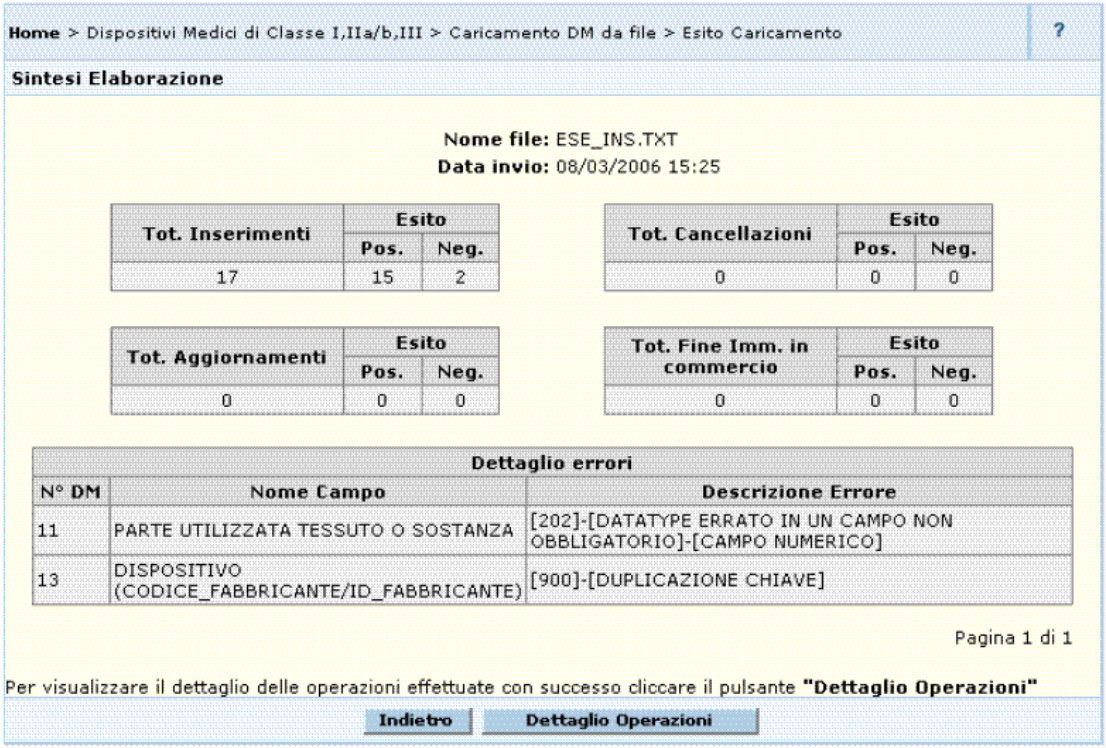
Field Name	**Description**
Nome File	The name of the file attached by the user, containing the DM's data
Data invio	Date in which the user uploaded the file
Esito	Indicates whether the file was examined by the automatic process of mass uploading of the DM contained in the database or not., and if so, whether the errors have been edited

Operations available

Action	**Description**	**Page name**
Ricerca	Runs the search with criteria in place and displays the list of files attached by the user	Same
Nuova ricerca	Clears the search criteria previously put in place	Same
Sintesi elaborazione	Allows the user t view the summary of the operations carried out and the details of any possible errors regarding he file selected.	UploadListaErrori

2.3.4.5 UploadListaErrori

This page allows the user to view the list of any errors which were verified during the processing of the file selected during the automatic mass uploading of the DM as well as a summary of the operations carried out.



Detail Fields

Field Name	Description
Nome File	The name of the file attached by the user, containing the DM data
Data invio	Date in which the user uploaded the file
N° DM	Position of the Dm within the file
Nome Campo	Name of field incorrectly evaluated.
Tot. Inserimento	Number of insertions carried out, by mass uploading, distinguishing between those with a positive result and those with a negative one.
Tot. Aggiornamenti	Number of upgrades carried out by mass uploading, distinguishing between those with a positive result and those with a negative one.
Tot. Cancellazione	Number of deletions carried out by mass uploading, distinguishing between those with a positive result and those with a negative one.
Tot. Fine immissione in commercio	Number put in Off-market carried out by mass uploading, distinguishing between those with a positive result and those with a negative one.

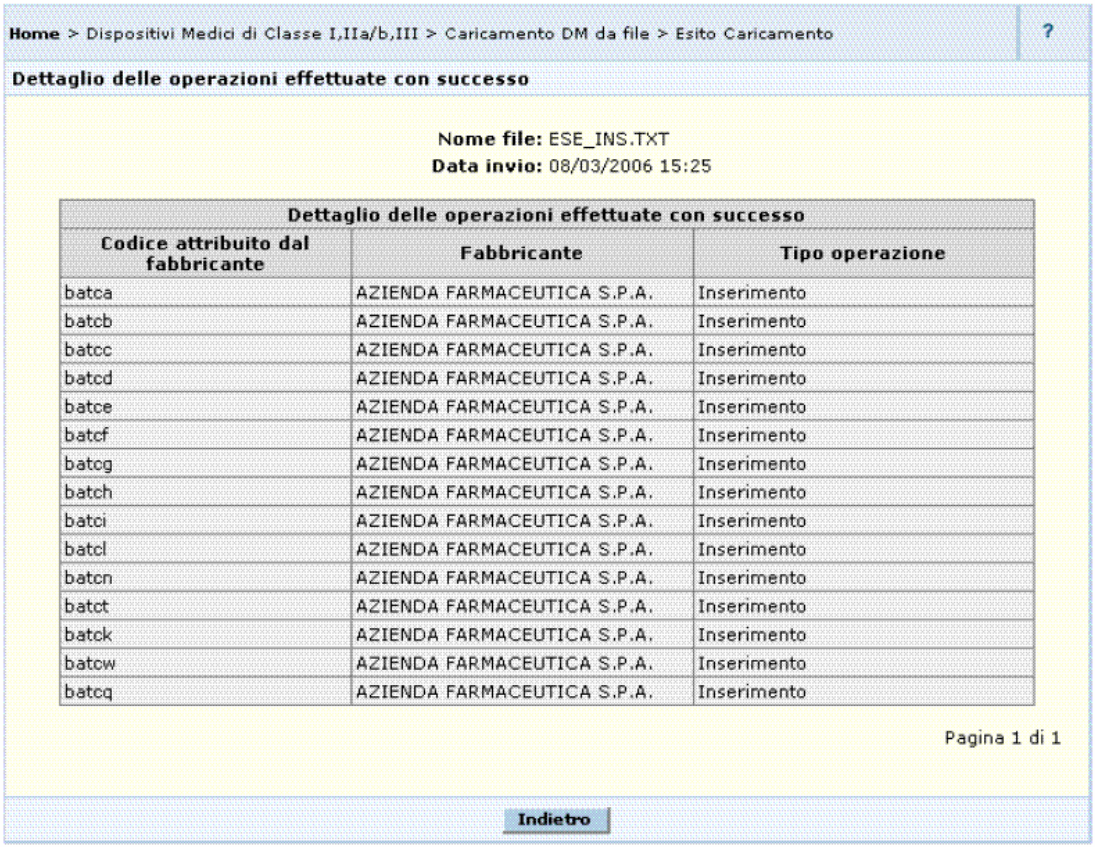
Descrizione Errore	Description of the error

Operations available

Action	Description	Page name
Indietro	Allows the user to return to the file list	Upload ListaFile
Dettaglio Operazioni	Allows the user to view the data of the operations carried out successfully	UploadSntesiFile

2.3.4.6 UploadListaSintesi

This page allows the user to view the list of operations carried out successfully by mass upload.



Detail Fields

Field Name	Description

Nome File	The name of the file attached by the user, containing the DM data
Data invio	Date in which the user uploaded the file
Codice attribuito dal Fabbricante	Code attributed to the DM by the Manufacturer.
Fabbricante	Business name of the DM Manufacturing company
Tipo operazione	Description of the type of operation carried out.

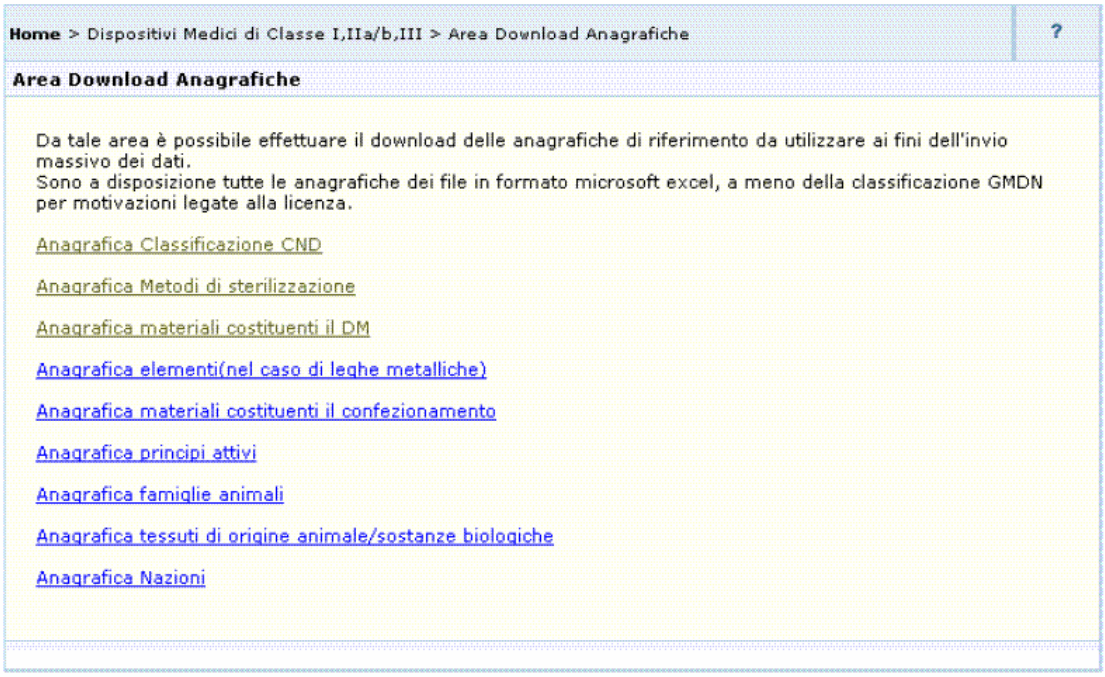
Operations available

Action	**Description**	**Page name**
Indietro	Allows the user to return to the error list	UploadListaErrori

2.3.4.7 AreaDownloadAnagrafiche

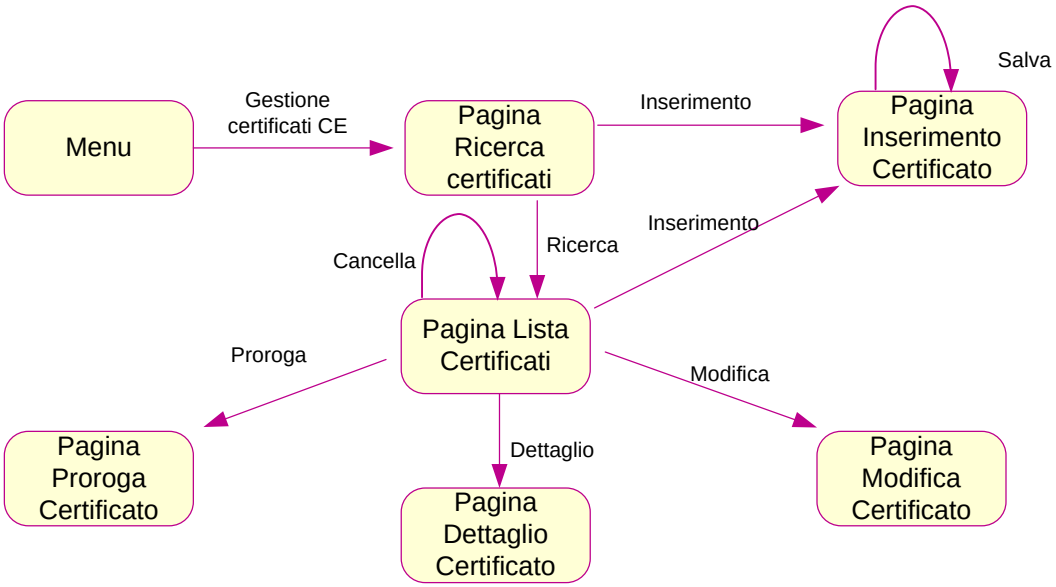
This page allows the Fab/Man/RIC/ASD user to download (clicking on the corresponding link) the following Database:

- CND Classification Database
- Methods of sterilisation Database
- Material that make up the DM Database
- Elements (in the case of metal) Database
- Material that make up the packaging Database
- Active ingredients Database
- Animal families Database
- Tissues of animal origin/biological substances Database
- Nations Database



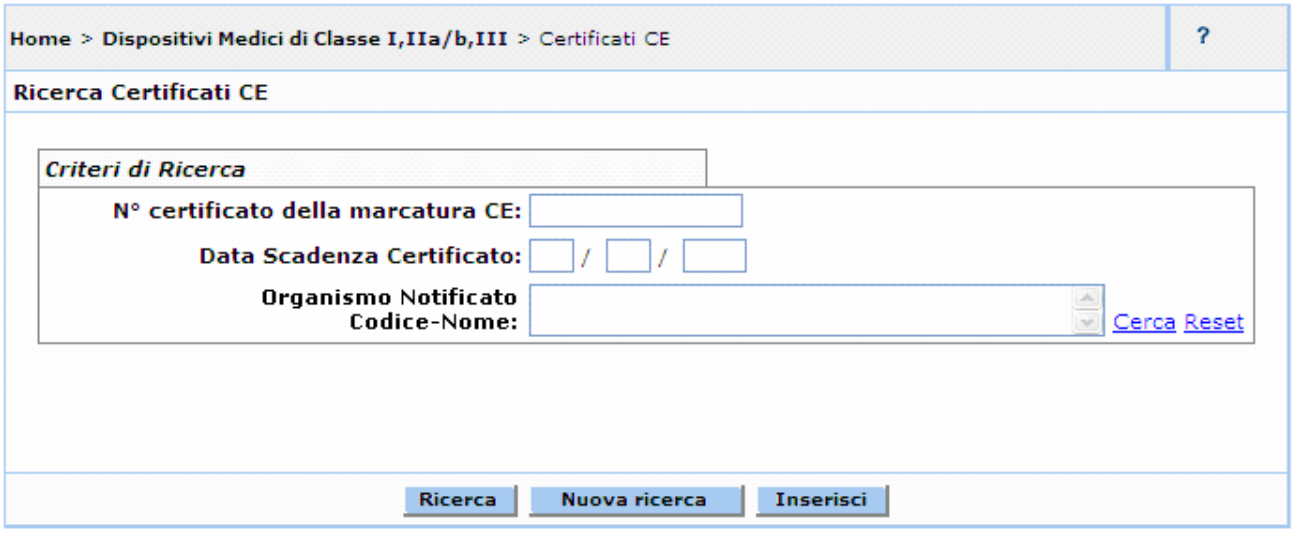
2.3.5. Menu option “Certificati CE”

Screen flowcharts:



2.3.5.1 Pagina Ricerca Certificati

Having clicked on “Certificati CE > Gestione Certificati CE” on the menu, a page appears which allows the user to define the search criteria of the EC certificates. To activate a search of these certificates, the user must define at least one margin.
From this page, the user may also access the insertion page of a new certificate clicking on the “Inserisci” button.



Fields Details

Field Name	Description
N Certificato della marcatura CE	Identification number of the EC certificate
Data Scadenza Certificato	Expiry date of the Certificate
Organismo Notificato – Codice - Nome	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the "Cerca" link; a look-up will open from which it will be possible to search for the organization notified by code and name.

Operations available:

Action	Description	Page Name
Ricerca	Runs a search of the certificates on the basis of the criteria inserted	Pagina Lista Certificati
Nuova ricerca	Clears the search criteria previously defined	Same
Inserisci	Allows access to the insertion page of a new EC certificate	Pagina Inserimento Certificato

2.3.5.2 Pagina Lista Certificati

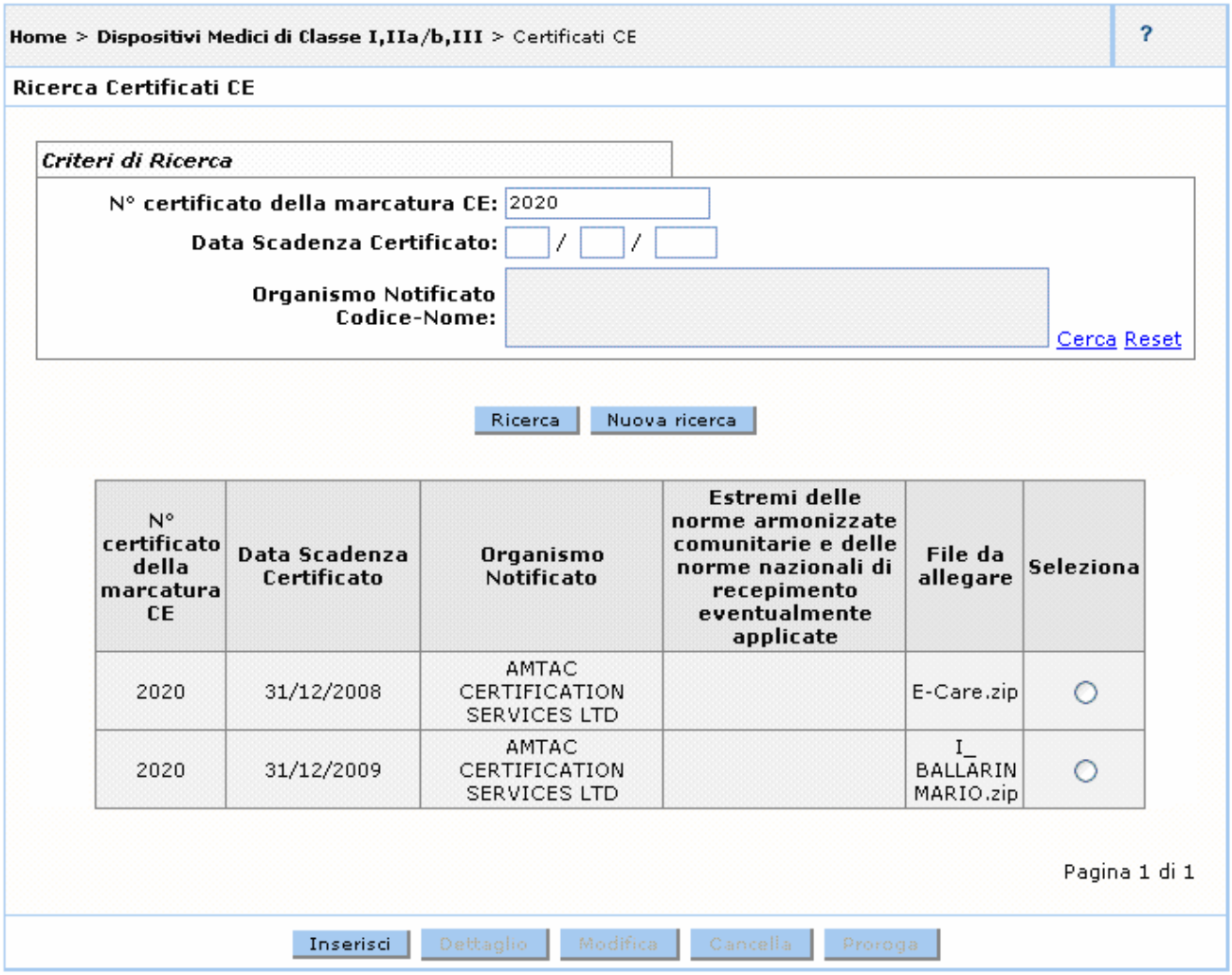
This page displays the list of the EC certificates which correspond to the criteria defined in the relative search page. For every certificate the following information is displayed:

- the certificate number of the EC stamp
- the expiry date
- the organization notified which issued it
- the essential details of the National and Community harmonized norms acknowledged and eventually applied

- the file attached containing the image of the certificate

From the page the user can ask for the insertion of a new certificate clicking on the always available “Inserisci” button.
Choosing a certificate from the list, the user will also be able to do the following:

- visualize the “Dettaglio” of the certificate;
- ask for the “Modifica” of the certificate only if the certificate selected has no extension and no medical devices validated or published inserted;
- ask for the “Cancellazione” of the certificate only if the certificate selected has no extension and no medical devices validated or published inserted. Activating the button “Cancella” the system will ask the user to give a voluntary confirmation to delete the certificate selected and if so, it will proceed to the cancellation. Then the list of the remained certificates will be visualized;
- access the “Proroga” page of a certificate only if the certificate selected has no extension inserted, or if there is an extension, it is related to at least one device validated or published.



-

Fields Details

Field Name	Description
N Certificato della marcatura CE	Identification number of the EC certificate
Data Scadenza Certificato	Expiry date of the Certificate
Organismo Notificato – Codice - Nome	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on the "Cerca " link; a look-up will appear from which it will be possible to search for the organization notified by code and name

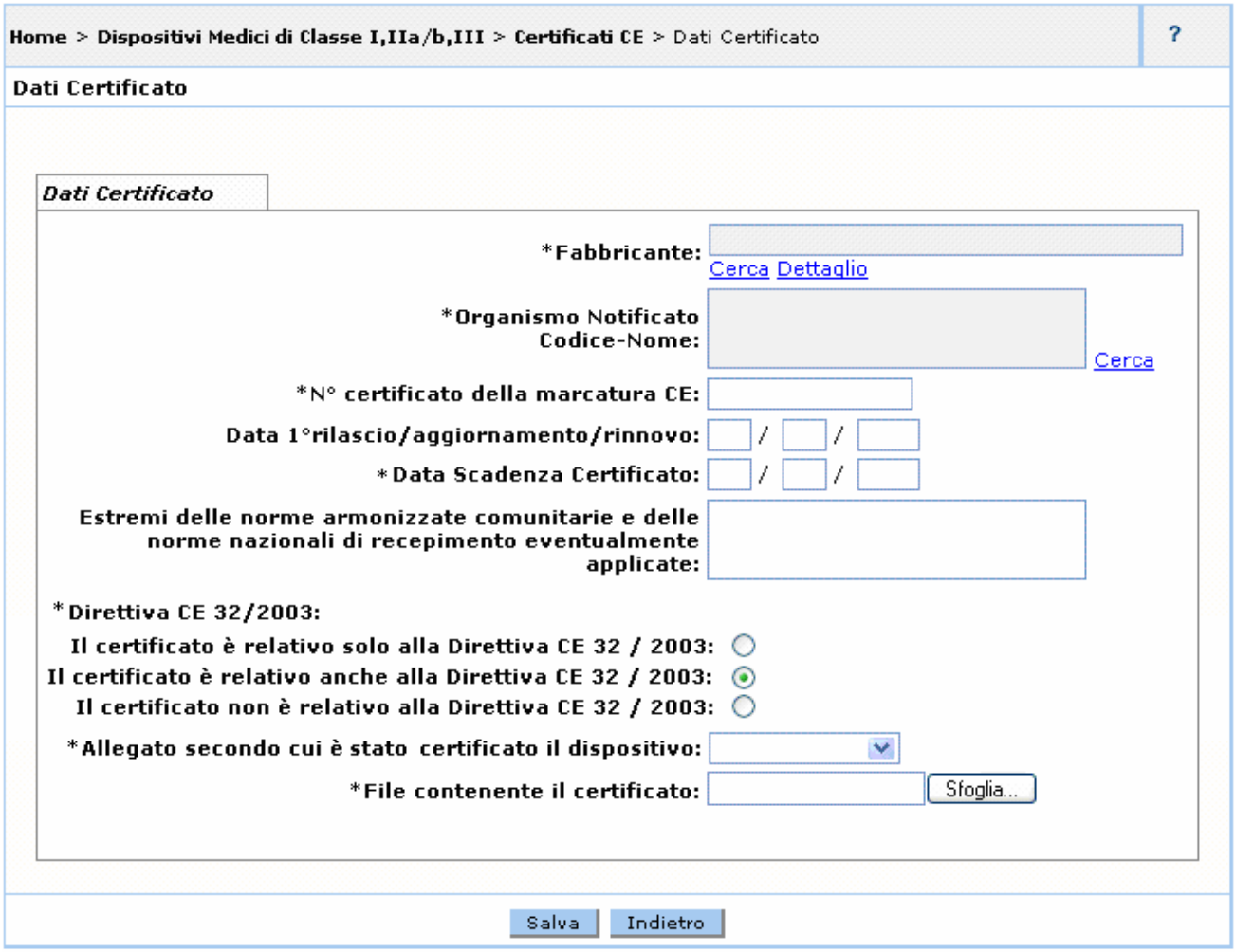
Operations available:

Action	Description	Page Name
Ricerca	Activates a search of the certificates on the basis of the criteria inserted	Pagina Lista Certificati

Nuova ricerca	Clears the search criteria previously defined	Same
Inserisci	Allows access to the insertion page of a new EC certificate	Pagina Inserimento Certificato
Dettaglio	Allows access to a detail page of the data associated with an EC certificate	Pagina Dettaglio Certificato
Modifica	Allows access to the modification page of the certificate selected	Pagina Modifica Certificato
Cancella	Deletes the certificate selected	Same
Proroga	Alows the user to access the extension page of the certificate selected	Pagina Proroga Certificato

2.3.5.3 Pagina Inserimento Certificato

This page allows the user to insert a new EC certificate.
The page is activated by clicking on the “Inserisci” button, present on the pages of search and visualization of the EC certificates list.
If the user inserts a certificate having “N.° certificato della marcatura CE” and “Organismo Notificato Codice – Nome” which coincide with those of a certificate already present in data base, the system will ask the user to insert such a certificate as an extension of that one which already exists (see paragraph 2.3.5.6)



Fields Details

Field Name	Description
Fabbricante	Indication of the manufacturer of the DM for which the certificate has been issued. To select a manufacturer it is necessary to click on link “Cerca”; there will appear a look-up from which it is possible to make a search
Organismo Notificato – Codice - Nome	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on link “Cerca”; a look-up will appear from which it will be possible to search for the organization notified by code and name
N Certificato della marcatura CE	Identification number of the EC certificate. Such number cannot contain blank spaces.
Data 1° rilascio/aggiornamento/rinnovo	Date of first release/update/renewal of the certificate
Data Scadenza Certificato	Expity date of the Certificate
Estremi delle	The essential details of the National an Community norms acknowledged during

norme armonizzate comunitarie e delle norme nazionali di recepimento eventualmente applicate	the fabrication of the DM
Direttiva CE 32 / 2003	States whether or not the certificate should be in compliance with EC Directive 32/2003: the user will have to indicate whether the certificate is relative only to EC Directive 32/2003, also to the EC Directive 32/2003 or is not relative to the ECDirective 32/2003. If the certificate is relative only to the EC Directive 32/2003, the field "Allegato secondo cui è stato certificato il dispositivo" mustn't be compiled.
Allegato secondo cui è stato certificato il dispositivo	Indication of the attachments according to which the device has been changed
File contenente il certificato	A .pdf file to be attached containing the image of the EC certificate. To attach this file it is necessary to use the "Sfoglia" button.

Operations available:

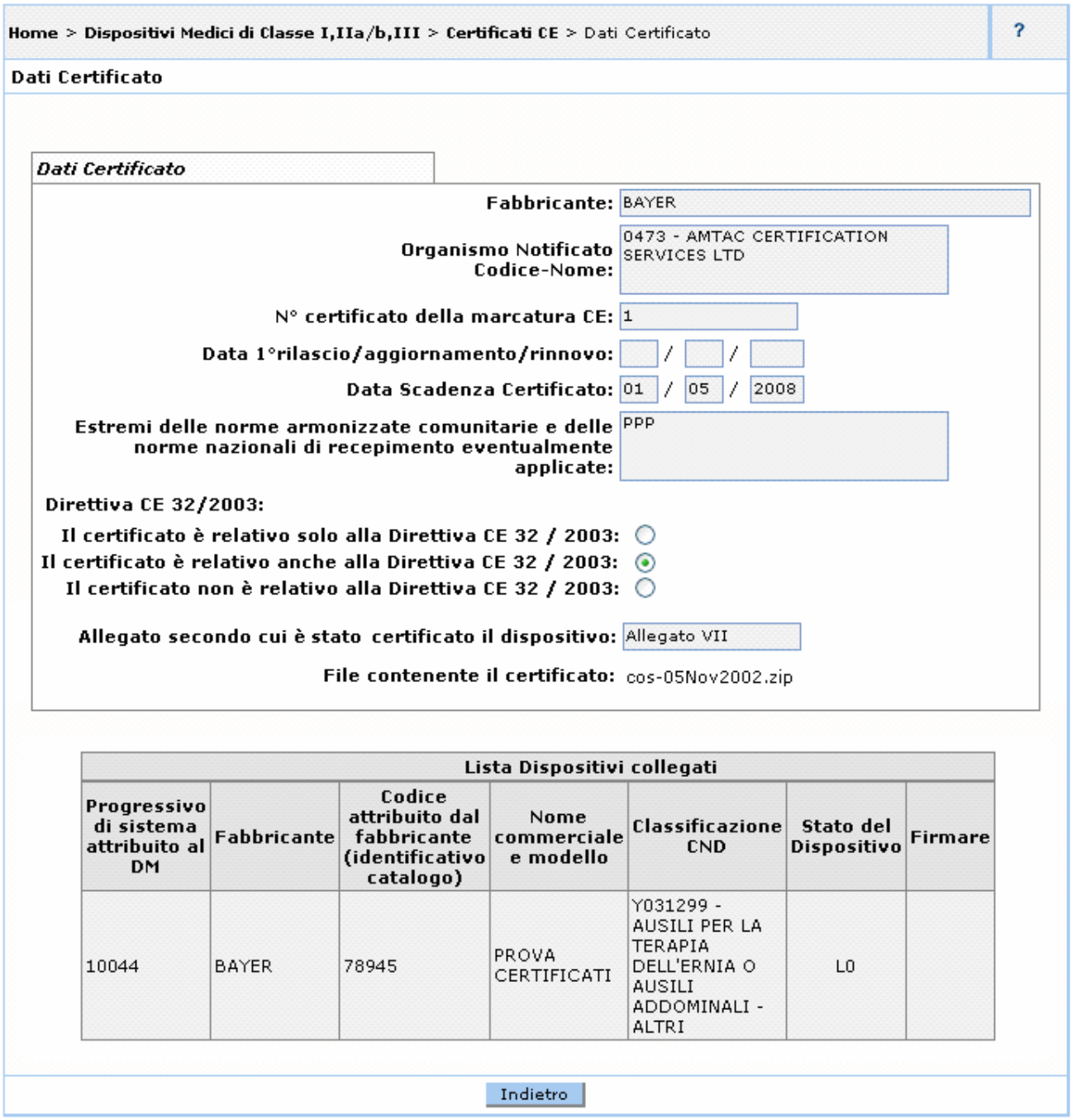
Action	**Description**	**Page Name**
Salva	Memorizes in the data base information relative to the certificate inserted e comes back to the previous page	Pagina Lista Certificati
Indietro	Voids the insertion and comes back to the previous page	Pagina Lista Certificati

2.3.5.4 Pagina Dettaglio Certificato

Activated by the page "Lista dei certificate", selecting a certificate and clicking on the "Dettaglio" button, the page allows the user to visualize, in non editable mode, the following detailed informations concerning a certificate:

- the manufacturer of the device or devices for which the certificate has been issued
- the organization notified which issued the certificate
- the certificate number of the EC stamp
- the date of issue/adjournment/renewal
- the expiry date of the certificate
- the essential details of the National and Community norms acknowledged and eventually applied
- indication of whether or not the certificate should be in compliance with EC Directive 32/2003
- the attachment according to which the device has been certficated
- the file attached containing the image of the certificate

Moreover, if the certificate is associated with the medical devices, the page will give evidence of it, displaying the list of the devices connected.

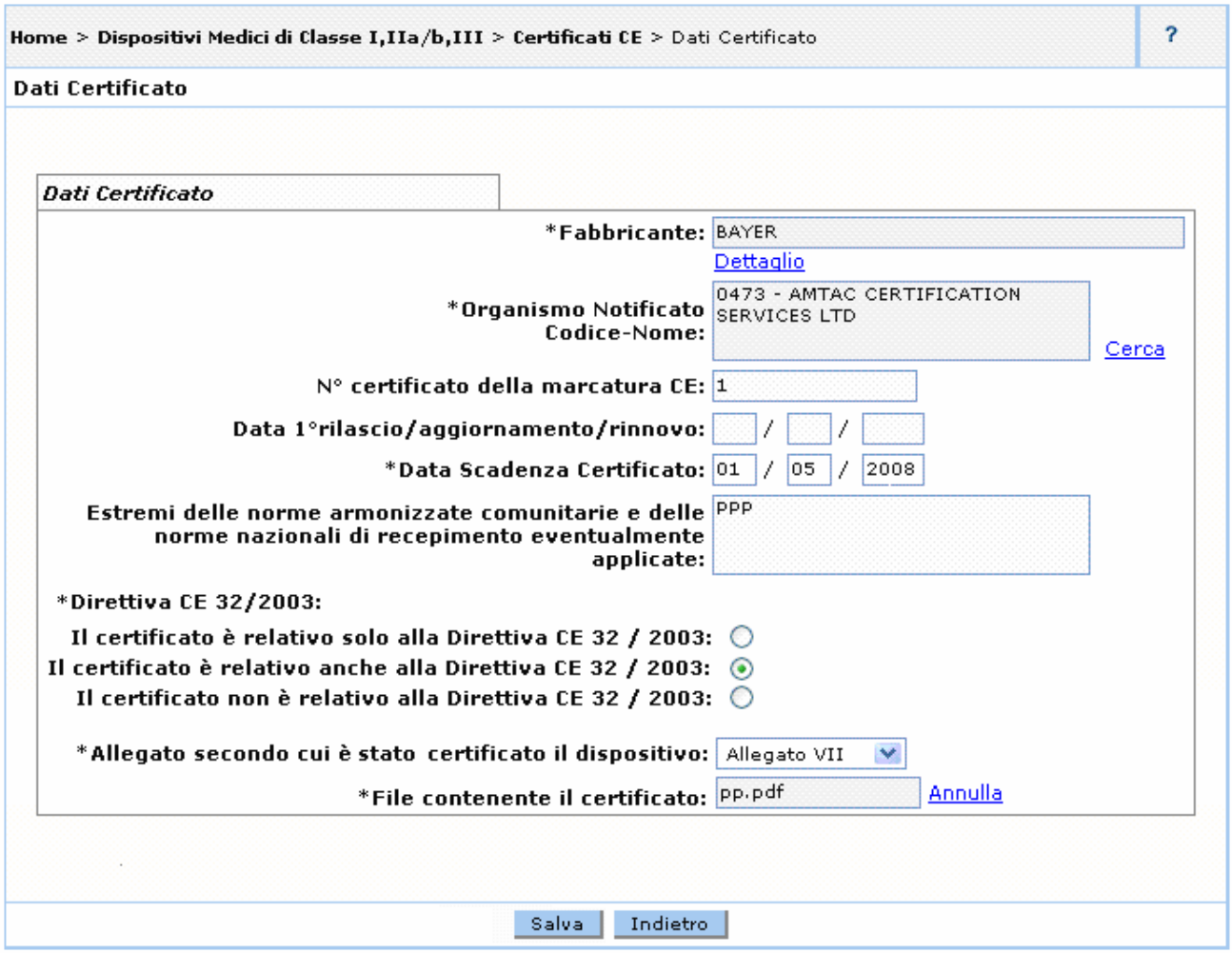


Operations available:

Action	Description	Page Name
Indietro	Comes back to the previous page	Pagina Lista Certificati

2.3.5.5 Pagina Modifica Certificato

This page is activated by the page “Lista certification”, selecting a certificate and clicking on button “Modifica”, allows the user to modify the data of the certificate which has no extension and no medical devices validated or published inserted.
If the certificate selected to be modified is associated with a medical device in processing, the name of the manufacturer becomes unmodifiable, talking in fact of the same manufacturer of the device associated.



Fields Details

Field Name	Description
Fabbricante	Indication of the manufacturer of the DM for which the certificate has been issued. To select a manufacturer it is necessary to click on link “Cerca”; there will appear a look-up from which it is possible to make a search
Organismo Notificato – Codice - Nome	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on link “Cerca”; a look-up will appear from which it will be possible to search for the organization notified by code and name
N Certificato della marcatura CE	Identification number of the EC certificate. Such number cannot contain blank spaces.
Data 1°	Date of issue/adjournment/ renewal of the EC Certificate

rilascio/aggiornamento/rinnovo	
Data Scadenza Certificato	Expity date of the Certificate
Estremi delle norme armonizzate comunitarie e delle norme nazionali di recepimento eventualmente applicate	The essential details of the National an Community norms acknowledged during the fabrication of the DM
Direttiva CE 32 / 2003	States whether or not the certificate should be in compliance with EC Directive 32/2003: the user will have to indicate whether the certificate is relative only to EC Directive 32/2003, also to the EC Directive 32/2003 or is not relative to the ECDirective 32/2003. If the certificate is relative only to the EC Directive 32/2003, the field "Allegato secondo cui è stato certificato il dispositivo" mustn't be compiled.
Allegato secondo cui è stato certificato il dispositivo	Indication of the attachments according to which the device has been changed
File contenente il certificato	A .pdf file to be attached containing the image of the EC certificate. To attach another file it is necessary to use the "Annulla" button. Then it is necessary to use the button "Sfoglia" to individuatea new .pdf file which supposed to be attached.

Operations available:

Action	**Description**	**Page Name**
Salva	Memorizes in the data base the modifications and comes back to the previous page	Pagina Lista Certificati
Indietro	Voids the insertion and comes back to the previous page	Pagina Lista Certificati

2.3.5.6 Pagina Dettaglio Proroga

Activated by the page "Lista certificati", selecting a certificate and clicking on the "Proroga" button, the page allows the user to insert an extension to a certificate exitent, if it has never been extended before, or if it has already been extended, it is associated with at least one device validated or published.

The page called is divided in two sections, in the first section "Dati certificate esistente" informations concerning the certificate in expiry are visualized in non editable mode, the second one "Dati certificate di proroga", gives the same informations which can be edited to allow the user to insert the data of the certificate of extension.
Moreover, if the certificate is associated with medical devices, the page will give evidence of it visualizing the list – with elements selected – of all the devices associated. In a specific there will

be visualized as the devoces in processing as those already validated and published that need a new signature.
Selecting the elements, the user is proposed to extend the association of all the medical devices associated already with the certificate extended to that of extension. All the same the user will be able to exclude, deselecting them, one or more medical devices, expressing this way a wish to exclude the fact that certificate of extension should be associated with DM selected.
That is why, if the user has had a wish to extend the association existent of the devices subscribed with the certificate extended to the certificate of extension, clicking on the "Salva" button, he will be directed to the signature page of such devices.

Fields Details

Field Name	**Description**
Fabbricante	Indication of the manufacturer of the DM for which the certificate has been issued. To select a manufacturer it is necessary to click on link "Cerca"; there will appear a look-up from which it is possible to make a search
Organismo Notificato – Codice - Nome	Indication of the code and name of the organization notified. This field cannot be edited. To select the code of the organization notified it is necessary to click on link "Cerca"; a look-up will appear from which it will be possible to search for the organization notified by code and name
N Certificato della marcatura CE	Identification number of the EC certificate. Such number cannot contain blank spaces.
Data 1° rilascio/aggiornamento/rinnovo	Date of issue/adjournment/ renewal of the EC Certificate
Data Scadenza Certificato	Expity date of the Certificate
Estremi delle norme armonizzate comunitarie e delle norme nazionali di recepimento eventualmente applicate	The essential details of the National an Community norms acknowledged during the fabrication of the DM
Direttiva CE 32 / 2003	States whether or not the certificate should be in compliance with EC Directive 32/2003: the user will have to indicate whether the certificate is relative only to EC Directive 32/2003, also to the EC Directive 32/2003 or is not relative to the ECDirective 32/2003. If the certificate is relative only to the EC Directive 32/2003, the field "Allegato secondo cui è stato certificato il dispositivo" mustn't be compiled.
Allegato secondo cui è stato certificato il dispositivo	Indication of the attachments according to which the device has been changed

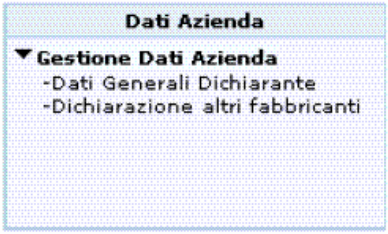
File contenente il certificato	A .pdf file to be attached containing the image of the EC certificate. To attach this file it is necessary to use the “Sfoglia” button.

Operations available:

Action	Description	Page Name
Salva	Inserts in the data base the certificate of extension, associating it with the devices selected, if the latter need a signature, calls back the page of signature	Pagina Lista Certificati
Indietro	Voids the insertion and comes back to the previous page	Pagina Lista Certificati

2.4 detailed description of the “Dati Azienda” functional area

Having gained access to the “dati Azienda” functional area, the features available are displayed on the left-hand menu.



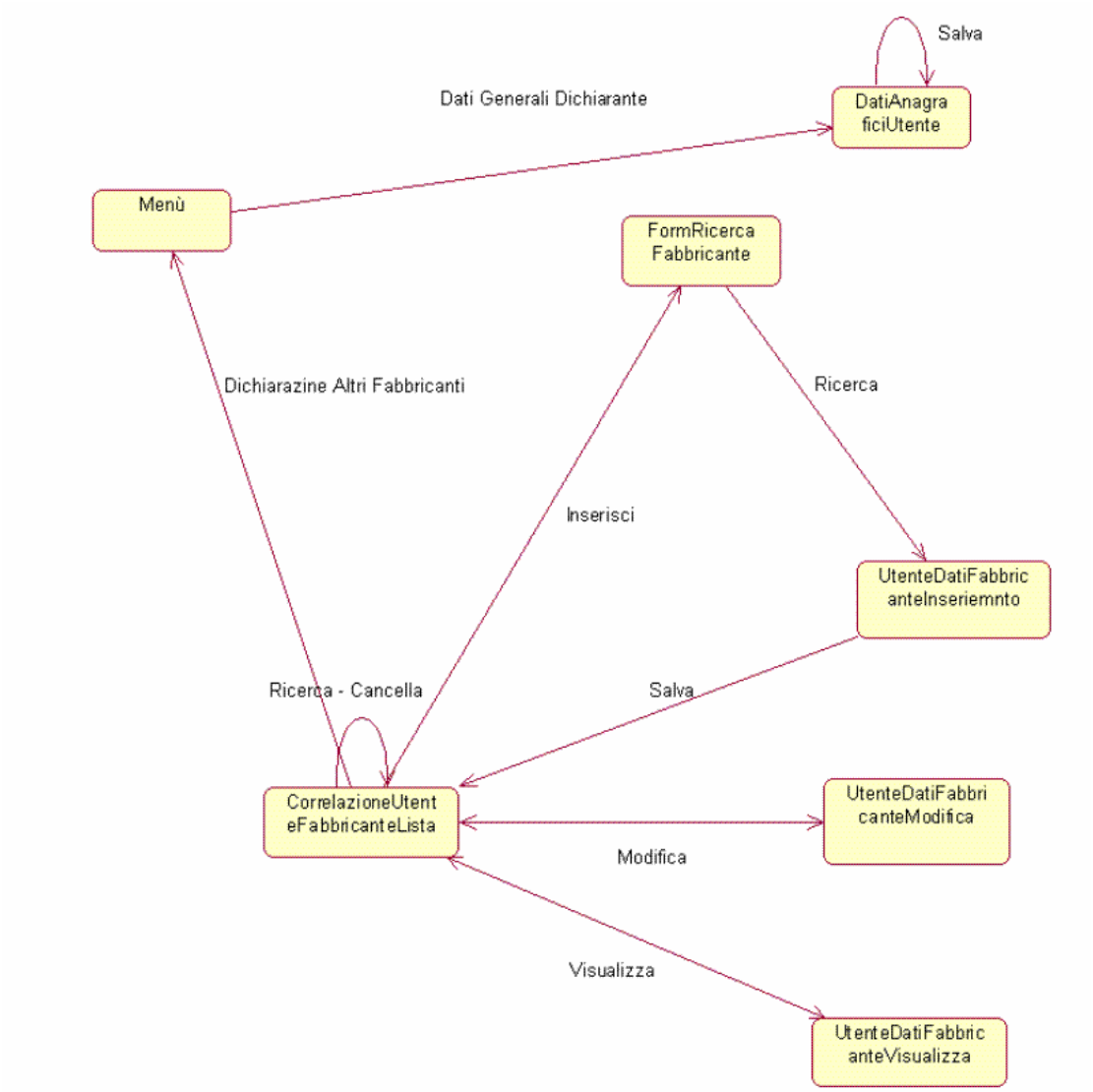
This area is only accessible by “FABBRICANTEDM” users.
In this area the Fab/Man/RIC/ASD user can perform two types of operations:

1. Integrate their own general data, which has already been indicated in the initial phase of access to the application (clicking on the lateral menu and choosing “Dati Generali Dichiarati”).
2. Indicate the manufacturers he represents (clicking on the lateral menu and choosing “Dichiarazione altri fabbricanti”).

The “Dati Generali Dicharati” feature must be used the first time the system is accessed by the user as all other functions remain disabled until such time as the user’s personal details have been completed. Therefore, only after this process, can the user gain access to the Dispositivi Medici di classe I, II a/b, III area.

2.4.1 "Gestione Dati azienda" Menu option

Screen flowchart:



2.4.1.1 DatiAnagraficiUtente

This page (which is accessed by clicking on the corresponding menu option "Dati Generali Dichiarante") allows the user to manage his own company's personal data.

This function must be used the first time the system is accessed by the user as all other functions remain disabled until such time as the user's personal details have been completed.

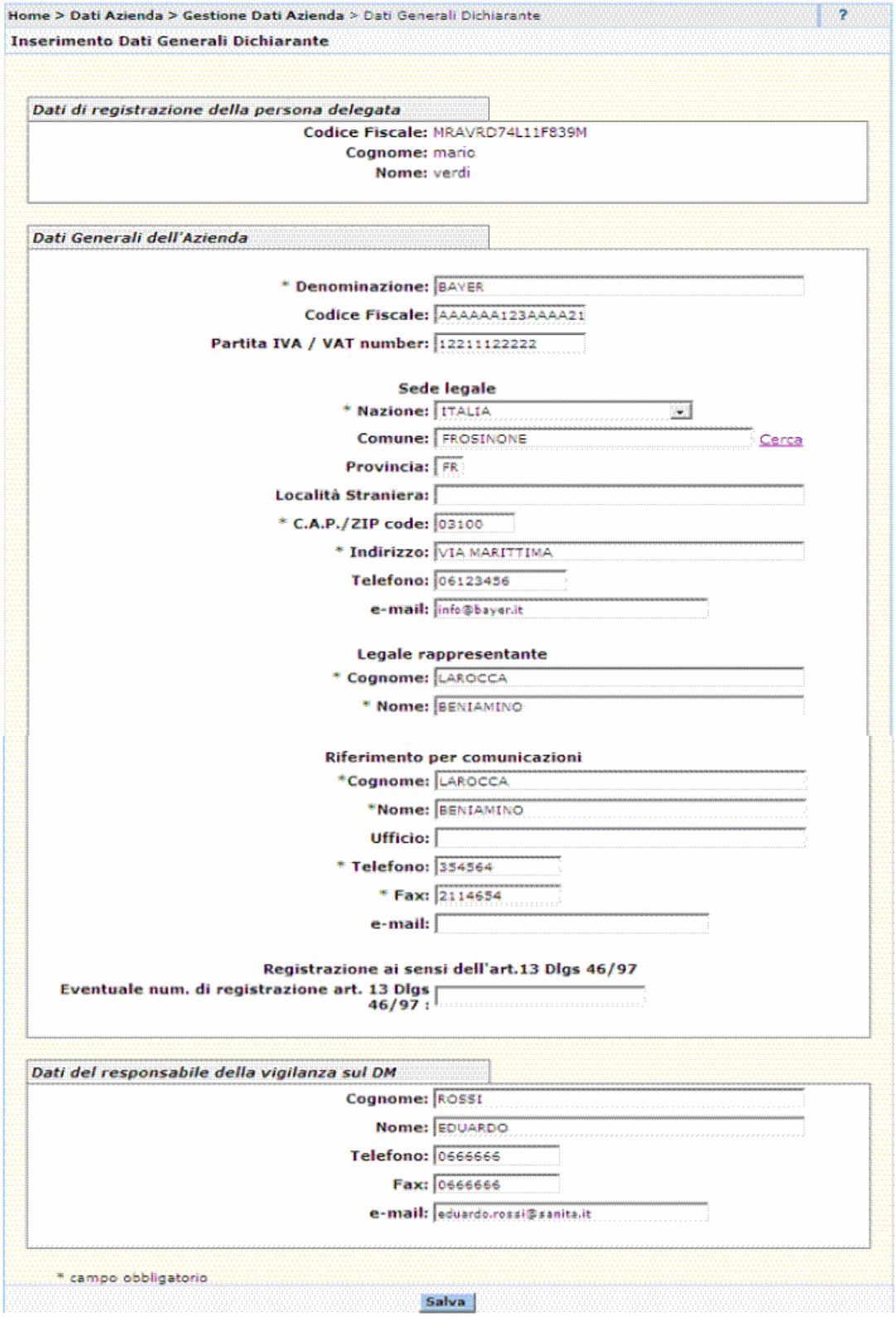
The page displays the general data (in read-only format) which the Fab/Man/RIC/ASD user has already indicated in the initial phase of access to the application. In particular, the following are indicated:

- Name, Surname and Fiscal code of the individual delegated
- Name, Fiscal Code and VAT number of the company that the user represents.

The user must complete the data regarding his company n reference to:

- Legal Headquarters (required)
- Legal representation (required)
- Contact reference
- Registration according to the provisions of Art.13 Legislative Decree 46/97 (optional)
- Details of the person responsible for vigilance of the DM (optional)

Having registered this information, the user must enter his electronic signature.



Detail Fields

Field Name	Description
Registration details of the delegated individual	
Codice Fiscale	Fiscal code of the delegated individual This field cannot be edited
Cognome	Surname of the delegated individual This field cannot be edited
Nome	Name of the delegated individual This field cannot be edited
General company data	
Nome	Name of the Manufacturer This field cannot be edited
Codice Fiscale	Fiscal code of the manufacturer. This field can only be edited this first time the user accesses the system. Such information is required for companies who have registered as having legal Headquarters in Italy.
Partita IVA/VAT Number	VAT number of the manufacturer. This field can only be edited this first time the user accesses the system. Such information is required for companies who have registered as having legal Headquarters in a country other than Italy.
General company data – legal Headquarters	
Sede Legale – Nazione	Nation of legal Headquarters of the manufacturer
Sede Legale – Comune	Council of the legal Headquarters of the manufacturer To select a town from the legal places of Headquarters, click on “Cerca”: a look-up will open where the user can search for a council. If the legal Headquarters is “Italia”, then “Comune” and “Provinca” must be indicated otherwise state the “Località straniera”
Sede Legale – Provincia	The foreign location of legal Headquarters of he manufacturer. If the legal Headquarters is “Italia”, then “Comune” and “Provinca” must be indicated otherwise state the “Località straniera”
Sede Legale– C.A.P/Zip code	Postcode or Zip code of the legal Headquarters of the Manufacturer
Sede Legale– Indirizzo	Address of the legal Headquarters of the Manufacturer
Sede Legale– Telefono	Telephone number of the legal Headquarters of the Manufacturer
Sede Legale– email	Email address of the legal Headquarters of the Manufacturer
General company data – legal representative	
Legale rappresentante– Cognome	Name of the Manufacturer ‘s legal representative.
Legale rappresentante– Nome	Surname of the Manufacturer ‘s legal representative.
General company data – Contact reference	
Riferimento per	Name of individual to contact to make official communications.

comunicazioni – Nome	Alternatively the following must be stated: • The name and surname of the individual to whom official communications must be referred. • The department to which official communications must be referred.
Riferimento per comunicazioni – Cognome	Surname of individual to contact to make for official communications. Alternatively the following must be stated: • The name and surname of the individual to whom official communications must be referred. • The department to which official communications must be referred.
Riferimento per comunicazioni – Ufficio	Office to contact to make official communications. Alternatively the following must be stated: • The name and surname of the individual to whom official communications must be referred. • The department to which official communications must be referred.
Riferimento per comunicazioni – Telefono	• Telephone number of the office of the person to contact in order to make official communications.
Riferimento per comunicazioni -Fax	• Fax number of the office of the person to contact in order to make official communications.
Riferimento per comunicazioni – e-mail	• Email address of the office of the person to contact in order to make official communications.
Registration in accordance with Art.13 Dlgs 46/97	
Eventuale num. Di registrazione art.13 Dlgs 46/97	Art.13 Dlgs 46/97 –Final registration no.
Data of person responsible for vigilance over DM	
Responsible della vigilanza sul DM – Nome	Name of the person responsible for vigilance over DM
Responsible della vigilanza sul DM – Cognome	Surname of the person responsible for vigilance over DM
Responsible della vigilanza sul DM – Telefono	Telephone number of the person responsible for vigilance over DM
Responsible della vigilanza sul DM – Fax	Fax number of the person responsible for vigilance over DM
Responsible della vigilanza sul DM – e-mail	Email address of the person responsible for vigilance over DM

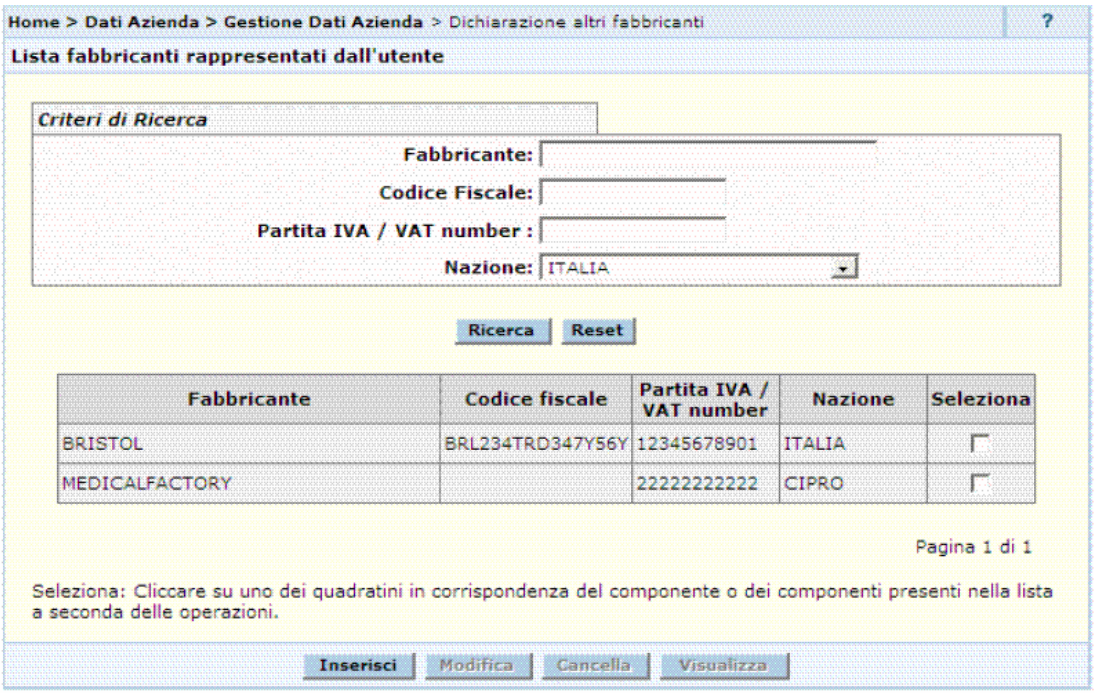
Operations available:

Action	**Description**	**Page name**

Salva	Allows the user to save the information inserted	Same

2.4.1.2 CorrelazioneUtentefabbricanteLista

This page allows the user to view the list of manufacturers that he represents and to filter the same list by stipulating one or more search criteria.



Search Detail Fields

Field Name	Description
Fabbricante	The name (or beginning) of the manufacturer can be indicated
Codice Fiscale	The Fiscal code of the manufacturer can be indicated
Partita IVA/VAT Number	The VAT number of the manufacturer can be indicated.
Nazione	The manufacturer's nationality can be selected from the mono-selection list.

Correlated Manufacturer List Detail Fields

Field Name	Description
Fabbricante	Name of the Manufacturer correlated.
Codice Fiscale	The Fiscal code of the manufacturer correlated
Partita IVA/VAT Number	The VAT number of the manufacturer correlated.
Nazione	The correlated manufacturer's nationality.

Operations available

Action	Description	Page name
Ricerca	Runs a search with criteria entered and displays the	Same

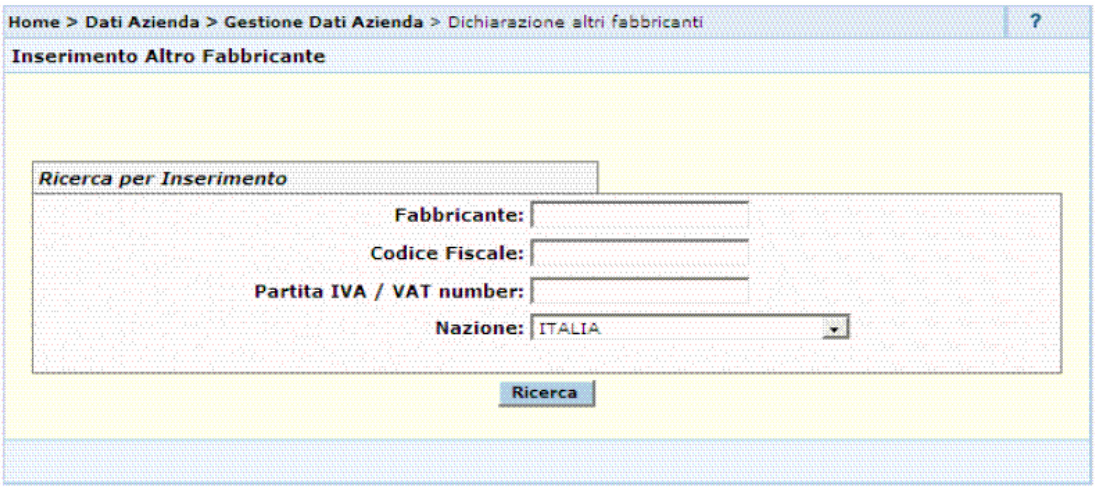
	list of products that match that criteria.	
Reset	Clears the search criteria previously put in place	Same
Inserisci	Grants the user access to the page that allows him to create a new link with another manufacturer.	UtenteDatiFabbricante Inserimento
Modifica	Grants the user access to the data page of the Manufacturer selected in order to edit the details	UtenteDatiFabbricante Modifica
Visualizza	Grants the user access to the data page of the Manufacturer selected in read-only format	UtenteDatiFabbricante Visualizza
Cancella	Allows the user to delete a link with a selected Manufacturer.	Same

2.4.1.3 FormRicercaFabbricante

This page allows the user to run a search of a manufacturer he represents, to be indicated.
Other than the nation, the fiscal code or the VAT number must be specified as search criteria.

Should the search have a positive outcome, i.e. the manufacturer is present in the database, the information resulting from the search on the Manufacturer will be displayed.

Should the search have a negative outcome, i.e. the manufacturer is not present in the database, the data entry fields of a new Manufacturer will be displayed.



Search Detail Fields

Field Name	Description
Fabbricante	The manufacturer can be indicated
Codice Fiscale	The Fiscal code of the manufacturer can be indicated
Partita IVA/VAT Number	The VAT number of the manufacturer can be indicated.
Nazione	The manufacturer's nationality can be selected from the mono-selection list.

	The default setting displays “Italia

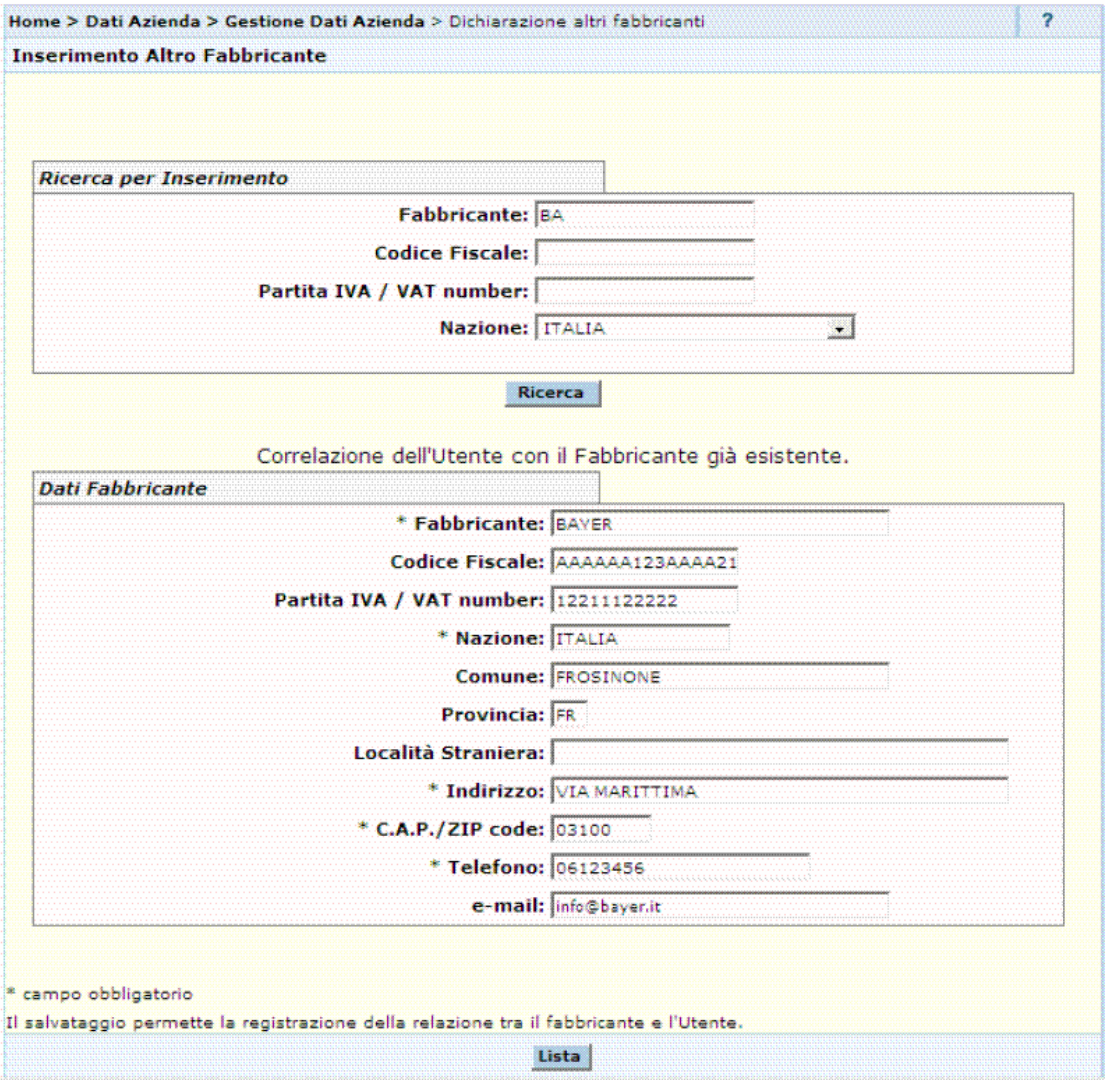
Operations available

Action	**Description**	**Page name**
Ricerca	Runs a search with criteria entered allowing the existence of the manufacturer with whom the user wishes to be linked, to be verified.	UtentiDatiFabbricante Inserimento.

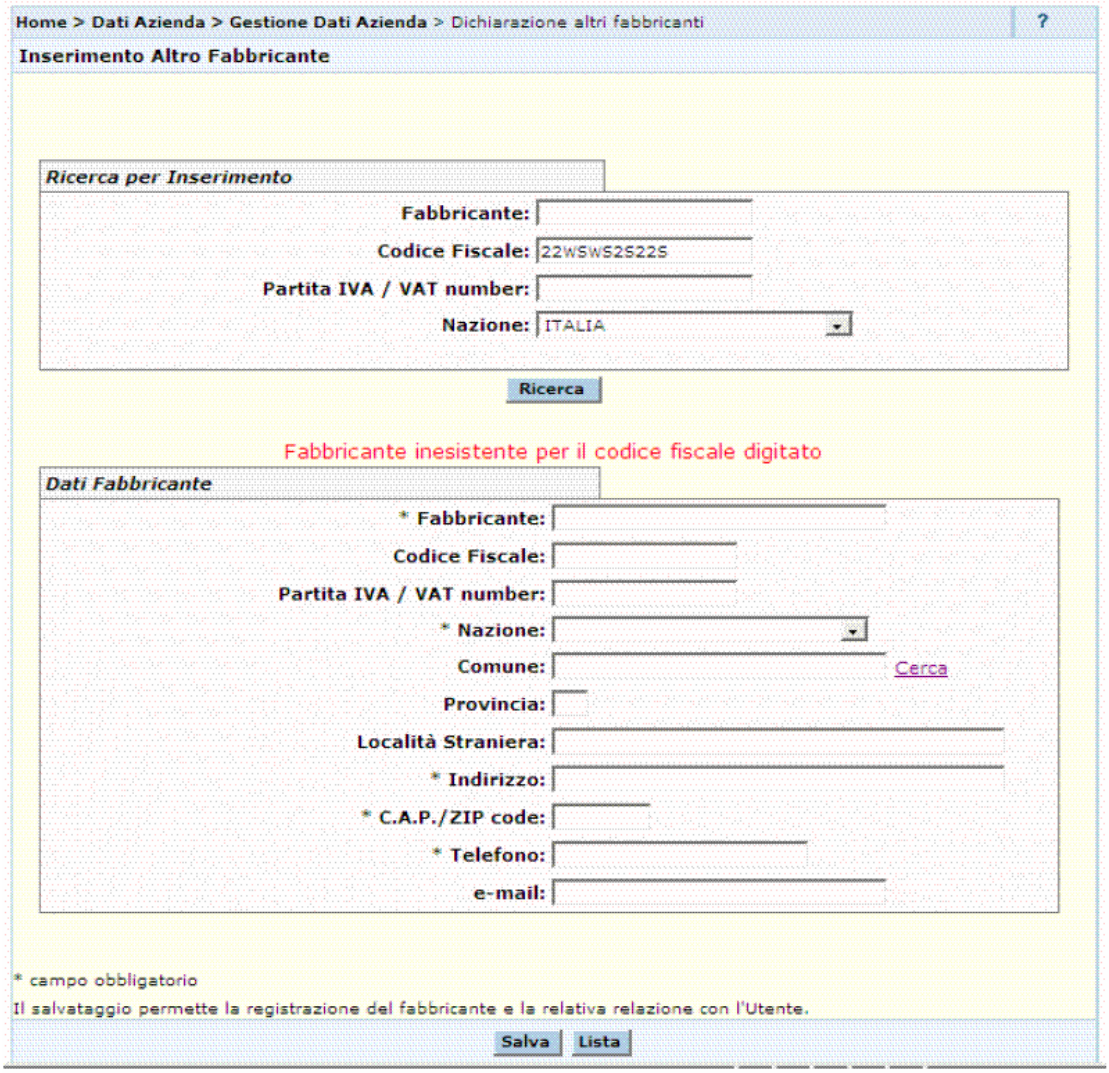
2.4.1.4 UtenteDatiFabbricanteInserimento

This page allows the user to link a new manufacturer to himself.

If the manufacturer (after having carried out the search, see previous paragraph) is present in the database, the information on the Manufacturer resulting from the search will be displayed in the “Dati Fabbricante” box. Then clicking on the “Salva” button the link between the user and the manufacturer is created.



If the manufacturer (after having carried out the search, see previous paragraph) is not present in the database, the “Dati Fabbricante” fields are left empty so that the user can enter the information regarding a new manufacturer. Then clicking on the “Salva” button the manufacturer is inserted into the database and subsequently the system creates a link between the user and the manufacturer entered.



Search Detail Fields

Field Name	Description
Codice Fiscale	The Fiscal code of the manufacturer can be indicated
VAT number	The VAT number of the manufacturer can be indicated.

Nazione	The manufacturer's nationality can be selected from the list. The default setting displays "Italia".

Manufacturer Data Fields

Field Name	**Description**
Fabbricante	Name of the manufacturer.
Codice Fiscale	Fiscal code of the manufacturer. This field can only be edited in the insertion phase. Required if Italy has been indicated as the Nation.
Partita IVA/VAT number	VAT number of the manufacturer. This field can only be in the insertion phase. Required if the Nation indicated is a country other than Italy.
Nazione	Nationality of the manufacturer
Comune	City of the manufacturer. To select a city, click on "Cerca": a look-up will open where the user can search for the city. If the legal Headquarters is "Italia", then "Comune" and "Provinca" must be indicated, otherwise state the "Località straniera"
Provincia	Province of the manufacturer. To select a Province, click on "Cerca": a look-up will open where the user can search for the Province. If the legal Headquarters is "Italia", then "Comune" and "Provinca" must be indicated, otherwise state the "Località straniera"
Località Straniera	The foreign location of the manufacturer. If the nation was identified as "Italia" in the insertion phase, then "Comune" and "Provinca" must be indicated, otherwise state the "Località straniera"
Indirizzo	Address of the Manufacturer
C.A.P/Zip code	Postcode or Zip code of the Manufacturer
Telefono	Telephone number of the Manufacturer
Email	Email address of the Manufacturer

Operations available

Action	**Description**	**Page name**
Ricerca	Runs a search with criteria entered allowing the existence of the manufacturer with whom the user wishes to be linked, to be verified.	Same
Salva	Saves the link with the manufacturer selected or inserted	CorrelazioneUtenteFabbricanteLista.
Lista	Allows the user to return to the list of manufacturers linked to the user	CorrelazioneUtenteFabbricanteLista.

2.4.1.5 UtenteDatiFabbricanteModifica

This page allows the user to edit the data of the Manufacturer selected. The user can only edit the data of manufacturers that he has entered personally.

However, the data of companies that also have other users acting as manufacturers, may no longer be edited.
Those users (who evidently registered in a later phase) may then edit the data regarding the companies in question, using the “Gestione Dati Azienda>Dati Generali Dichiarante” feature.

Data Fields

Field Name	**Description**
Fabbricante	Name of the manufacturer. Cannot be edited.
Codice Fiscale	Fiscal code of the manufacturer. Cannot be edited.
Partita IVA/VAT number	VAT number of the manufacturer. This field can only be in the insertion phase. Required if the Nation indicated is a country other than Italy.
Nazione	Nationality of the manufacturer. Cannot be edited.
Comune	City of the manufacturer. To select a city, click on “Cerca”: a look-up will open where the user can search for the city. If the nation of the manufacturer is “Italia”, then “Comune” and “Provinca” must be indicated, otherwise state the “Località straniera”
Provincia	Province of the manufacturer. To select a Province, click on “Cerca”: a look-up will open where the user can search for the Province. If the nation of the manufacturer is “Italia”, then “Comune” and “Provinca” must be indicated, otherwise state the “Località straniera”
Località Straniera	The foreign location of the manufacturer. If the nation was identified as “Italia”, then “Comune” and “Provinca” must be indicated, otherwise state the “Località

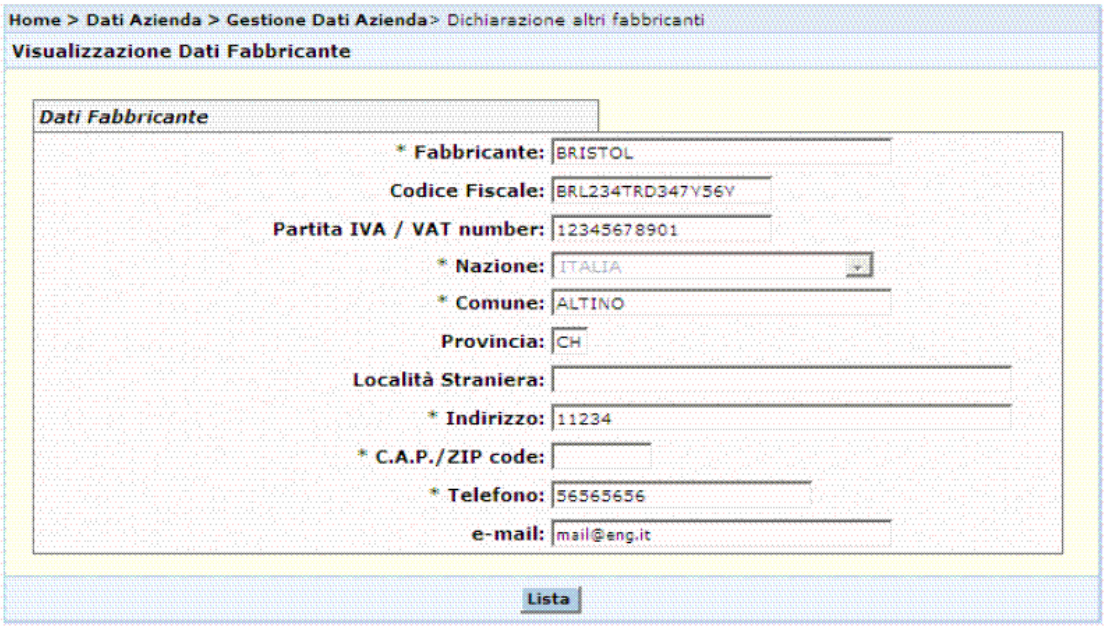
	straniera”
Indirizzo	Address of the Manufacturer
C.A.P/Zip code	Postcode or Zip code of the Manufacturer
Telefono	Telephone number of the Manufacturer
Email	Email address of the Manufacturer

Operations available

Action	Description	Page name
Salva (is present only if the user is authorised to edit the information of the Manufacturer selected)	Saves the changes made by the user.	CorrelazioneUtenteFabbricanteLista.
Lista	Allows the user to return to the list of manufacturers linked to the user	CorrelazioneUtenteFabbricanteLista.

2.4.1.6 UtenteDatiFabbricanteVisualizza

This page grants the user access to the data of the manufacturer selected in read-only format.



Data Fields

Field Name	**Description**
Fabbricante	Name of the manufacturer.
Codice Fiscale	Fiscal code of the manufacturer.
Partita IVA/VAT number	VAT number of the manufacturer.
Nazione	Nationality of the manufacturer. Cannot be edited.
Comune	City of the manufacturer.
Provincia	Province of the manufacturer.
Località Straniera	The foreign location of the manufacturer.
Indirizzo	Address of the Manufacturer
C.A.P/Zip code	Postcode or Zip code of the Manufacturer
Telefono	Telephone number of the Manufacturer
e-mail	Email address of the Manufacturer

Operations available

Action	**Description**	**Page name**
Lista	Allows the user to return to the list of manufacturers linked to the user	CorrelazioneUtenteFabbricanteLista.