INSTALLATION QUALIFICATION REPORT

for

STERICOOL Hydrogen Peroxide Plasma Sterilizer Range

A160S, A160D, A160SF, A160DF, A110S, A110D, A110SF, A110DF

GOA Teknoloji A.S

Ivedik OSB 1436.Sok No:14

Ostim Yenimahalle 06378– ANKARA TURKEY

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IQ – Device Origin and Identification

Device Series and Model:	……
Serial Number:	……
Device Description:	……
Manufacturer	GOA TEKNOLOJI A.S Ivedik OSB 1436.Sok No:14 Ostim Yenimahalle 06378 Ankara, TURKEY
Service Contract	……
Condition:	……
Date Received / Installed:	……
Installed Location:	……
Purchase Order Number:	……
Identification / Asset Number:	……

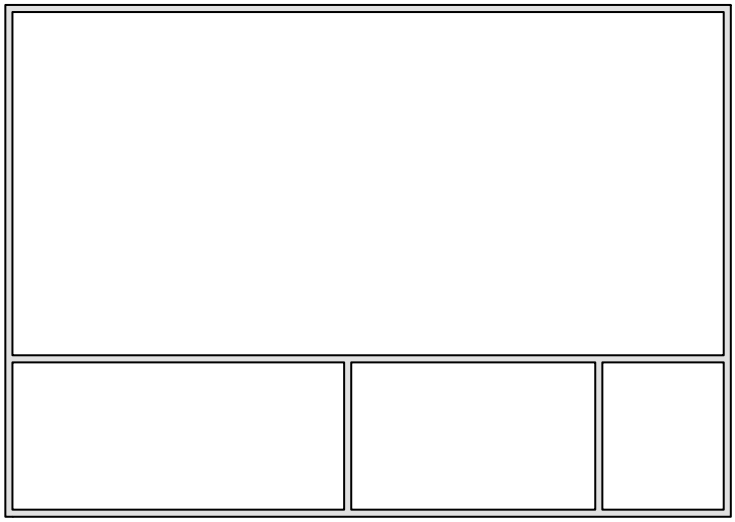
IQ – Device Specification

DEVICE PARAMETER	ACCEPTABLE
Chamber Size 110Lt / 160lt	YES / NO
Single Door / Double door	YES / NO
Front Loaded / Side loaded	YES / NO
240ml / 30ml Cartridge	YES / NO
Stainless / Aluminum Chamber	YES / NO
RFID / Barcode Sterilant reader	YES / NO
Mobility Wheels / Feet	YES / NO
Other Technical Specs	YES / NO

IQ – Environment and Site Check

OPERATING PARAMETERS	SPECIFIED RANGE	CONDITIONS MET
Air Exchanges	10 per Hour	YES / NO
Operating Temperature: **Storage Temperature:**	18°C–35°C -29°C–70°C	YES / NO
Heat Generation	Max at Advance cycles 10 KW	YES / NO
Maximum Relative Humidity	80% up to 30°C, decreasing linearly to 70% at 40°C non-condensing	YES / NO
Maximum Altitude	3000m	YES / NO
Supply Voltage & Frequency	Single Phase 220-240V@ 50/60H Phase 220-240V@ 50/60H	YES / NO
Maximum Current	16Amp	YES / NO
Earth Leakage protection	Yes and Max difference between live and earth 0.5V	YES / NO

IQ – Device Delivery and Documentation

Packaging Crate Inspection
Is there any damage to the packaging crate? **Yes/No?** **If Yes, please circle the appropriate location:**   
Comments:

Packaging List	PRESENT	MISSING
2x Trays		
Caster Wheels (2x with lock 2x without Lock)		
Oil Return Valves/Solenoids		
Catalytic Converter (Trap)		
Gate Valve		
Thermal Printer Paper		
Vacuum Pump Oil		
Independent Monitoring System (IMS): For compliance with ISO 14937. The Independent Monitoring System (IMS) is an optional feature thatmay be purchased and installed on the sterilizer. It is an independent data collection system that can be used for system validation or requalification. Madge Temp sensor and T Junction with Edwards pressure sensor and reader.		

Is there any damage to the Device or accessories: YES / NO?

If yes: Description of damage:

_____

_____

_____

_____

_____

Corrective action:

_____

_____

_____

_____

_____

Documentation Checklist	PRESENTED	MISSING
User Manual	YES / NO	YES / NO
Quick Guide Wall Poster	YES / NO	YES / NO
Installation Manual	YES / NO	YES / NO
Certificate of Conformity	YES / NO	YES / NO
Warranty Document	YES / NO	YES / NO
ADDITIONAL DOCUMENTATION	**REQUESTED**	**PRESENT**
Production OQ/PQ Test Certificate	YES / NO	YES / NO
Service Manual	YES / NO	YES / NO

IQ – Device Safety

MANUFACTURER SAFETY RECOMENDATIONS	CONFIRMATION
Allow enough space for the Device (See installation Manual)	YES / NO
Position on level Surface	YES / NO
Heavy load surface indoor to carry 450Kg	YES / NO
Mobility on Wheels	YES / NO
Water supply accessible in case of emergency?	YES / NO
Read User Manual before operating	YES / NO
Comments:	

IQ – Assembly and Installation

Assembled and Installed By Trained Technician/ Engineer? Yes / No

Name of the Engineer or Technician:

Installation Procedure	STATUS	Discrepancy
Unpack and retain Packing	YES / NO	
Assembly done as per the Installation Manual?	YES / NO	
Connected to Power supply?	YES / NO	
Quick Guide poster and User manual available by the sterilizer?	YES / NO	

Comments:

Installation Qualification Summary Report

Device:	**Manufacturer:**

Assessment of Complete Installation Qualification:

Is there a Deviation? YES / NO

IF YES LIST THE DEVIATIONS BELOW

Deviation	Impact on Operation	Justification for acceptance

Successful completion of the preceding activities and checks indicates that this Device has been satisfactorily delivered and installed. The Device has passed the Installation Qualification procedure and may now be submitted for Operational Qualification

IQ Completed By:		**Date:**
Deviations Approved By:		**Date:**
IQ Approved By:		**Date:**