EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

(EU) 2017/745 Medical Device Regulation Annex IX
Chapter I and III

Certificate Number: MDR.2292-2025/0017

Manufacturer Name	: Sterilmed Medical Elektrik Elektronik Otomasyon İnşaat Gıda Sanayi ve Dış Tic. Ltd. Şti.
Manufacturer Address	: Malıköy Başkent Osb. Mah. 18 Cad. No: 43 Sincan ANKARA / TÜRKİYE
Single Registration Number-SRN	: TR-MF-000018720
Authorized Representative Name (If any)	: Not Applicable.
Authorized Representative Address	: Not Applicable.
Device/Device Group Name **Detailed information is in the attached device list.*	: Steam Sterilizer Washer Disinfector Low Temperature Sterilizer

Based on the conformity assessment of the quality management system of the above-mentioned manufacturer according to Annex IX Chapter I and Chapter III of (EU) 2017/745 Medical Device Regulation, UDEM A.Ş. declares that the relevant requirements are met for the products listed in this certificate

The manufacturer has established, documented and implemented a quality management system that is subject to periodic surveillance assessments by UDEM A.Ş. in accordance with Annex IX Chapter I Section 3 of the related regulation.

All relevant reports starting with the number UDEM.0025 of the customer organization referred to below summarize the outcome of the assessments/reviews and refer to the relevant common specifications, if any, harmonized standards and test reports. Upon request, these reports are available in UDEM A.Ş. records in accordance with Section 10 of Chapter II of Annex XII of the MDR. For Class III and certain Class IIb implantable devices referred to in the second subparagraph of Article 52(4) of (EU) 2017/745 Medical Device Regulation covered by this certification, an EU Technical Documentation Assessment Certificate is required before they can be placed on the market.

Customer Number	: UDEM.0025
Issue Date	: 03.06.2025
Revision Date/No	: - / -
Validity Date	: 02.06.2030
Previous Certificate(s) No., if any	: Not Applicable.

APPROVED 2292

General Manager
Stamp - Signature

UDEM A.Ş. is a Notified Body under the (EU) 2017/745 Medical Device Regulation. Notified Body No: 2292

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ANNEX: DEVICE LIST WITHIN THE SCOPE OF THE CERTIFICATE

DEVICE PRODUCT/DEVICE GROUP	RISK CLASS	EMDN CODE	INTENDED USE *Should be specified only for class IIb and class III devices.*
STEAM STERILIZER MODEL; SS40 SS50 SS67 SS67H SS40F SS50F SS67F	IIa	Z12011304	-
WASHER DISINFECTOR MODEL; WD1 WD2 WD3	IIb	Z12011301	Washing and disinfection devices are used to effectively remove and disinfect organic and inorganic dirt on devices during the preparation of medical devices for reuse.
LOW TEMPERATURE STERILIZER MODEL; PL1 PL2 PL3 PL4	IIa	S9001	-

**Limitations on the conditions of the certificate: Not Applicable.*

CERTIFICATE HISTORY		
Rev. No.	**Rev. Date**	**Revision Explained**
00	03.06.2025	Initial Certification

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