EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

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

Certificate Number: MDR.2292-2026/0047

Manufacturer Name	: RST Medikal Tıbbi Cihazlar Otomasyon Makina İthalat İhracat San. Ltd. Şti.
Manufacturer Address	: İvedik OSB Mah. 1351 Cad. No: 11 Yenimahalle ANKARA / TÜRKİYE
Single Registration Number-SRN	: TR-MF-000021342
Authorized Representative Name (If any)	: Not Applicable.
Authorized Representative Address	: Not Applicable.
Device/Device Group Name **Detailed information is in the attached device list.*	: Autoclave (Steam Sterilizer) Washer-Disinfector Hydrogen Peroxide 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.0150 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.0150
Issue Date	: 24.07.2026
Revision Date/No	: - / -
Validity Date	: 23.07.2031
Previous Certificate(s) No., if any	: Not Applicable.

UDEM 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.*
Autoclave (Steam Sterilizer) R-SERIES, RS-SERIES, RST-SERIES: 160 D, 250 D, 450 D, 550 D, 670 D, 830 D, XL-645 D, XL-800 D, XL-1000 D, XL-1290 D, XL-1500 D, XL-2100 D; 160 S, 250 S, 450 S, 550 S, 670 S, 830 S, XL-645 S, XL-800 S, XL-1000 S, XL-1290 S, XL-1500 S, XL-2100 S; M-160 D, M-250 D, M-450 D, M-550 D, M-670 D, M-830 D, M-XL -645 D, M-XL -800 D, M-XL-1000 D, M-XL-1290 D, M-XL-1500 D, M-XL-2100 D; M-160 S, M-250 S, M-450 S, M-550 S, M-670 S, M-830 S, M-XL-645 S, M-XL-800 S, M-XL-1000 S, M-XL-1290 S, M-XL-1500 S, M-XL-2100 S R-D: 100 D, 100 S, M-100 D, M-100 S	IIa	Z12011304	-
Washer-Disinfector RST MEDİKAL: WD-100XS, WD-100XD, WD-150XS, WD-150XD, WD-200XS, WD-200XD, WD225-S, WD-225-D; WD290-S, WD-290-D, WD-360-S, WD-360-D, WD-450-S, WD-450-D BİONSTER: BSWD-100BS, BSWD-100BD, BSWD-150BS, BSWD-150BD, BSWD-200BS, BSWD-200BD, BSWD-225-S, BSWD-225-D; BSWD-290-S, BSWD-290-D, BSWD-360-S, BSWD-360-D, BSWD-450-S, BSWD-450-D	IIb	Z12011301	This is an automatic washer-disinfector intended for use in hospitals and laboratories. It has been developed for medical purposes in accordance with TS EN ISO 15883 standards and the requirements of Regulation (EU) 2017/745 (MDR). The device is intended for the automatic cleaning and thermal disinfection of items used in healthcare settings, including anesthesia equipment, endoscopes, dental instruments, medical instruments, surgical hand instruments, baby bottles, pacifiers, bedpans, urinals, slippers, and similar products. It is a medical device intended to ensure the effective cleaning and disinfection of these items.
Hydrogen Peroxide Sterilizer RST MEDİKAL: RH-50S, RH-50D, RH-80S, RH-80D, RH-100S, RH-100D, RH-130S, RH-130D; RH-150S, RH-150D, RH-200S, RH-200D, RH-300S, RH-300D BİONSTER: BH-50S, BH-50D, BH-80S, BH-80D, BH-100S, BH-100D, BH-130S, BH-130D; BH-150S, BH-150D, BH-200S, BH-200D, BH-300S, BH-300D	IIa	Z12011309	-

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

CERTIFICATE HISTORY		
Rev. No.	**Rev. Date**	**Revision Explained**
00	24.07.2026	Initial Certification

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

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