EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

According to Annex IX-Chapters I and III of the Regulation (EU) 2017/745 on Medical Devices

Certificate No.: 2975-MED-2620501

Manufacturer:	**MEDİSOLARİS SAĞLIK HİZMETLERİ SAN. VE TİC. LTD. ŞTİ.** Fatih Mahallesi 1191. Sokak No:28/1 B Blok Gaziemir, İzmir, Türkiye
Manufacturer's SRN:	TR-MF-000015946
Device Information:	**See Section 2**
Report No.:	MD0018-P001-R01
Specific Conditions or Limitations:	N/A
Revision History:	**See Section 3**

SZUTEST Konformitätsbewertungsstelle GmbH, Notified Body 2975, declares that the aforementioned manufacturer has implemented a quality management system according to Annex IX Chapters I and III of the Regulation (EU) 2017/745 on medical devices. This quality system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Regulation. The approved quality system is subject to surveillance pursuant to Annex IX Chapter I Section 3 of the Regulation and unannounced site audits.

The Report(s) stated above summarize the conformity assessment results and include references to the relevant CS, harmonized standards, sampled/reviewed technical documentation, and test reports.

SZUTEST Konformitätsbewertungsstelle GmbH must be informed of any substantial changes in the design and/or construction of the device(s).

For placing on the market class III devices and class IIb devices referred to in the second subparagraph of Article 52(4) covered by this certificate, an EU Technical Documentation Assessment certificate according to Annex IX Chapter II is required.

First Issue Date: 24-07-2026
Revision Date: 24-07-2026
Revision No.: 00
Validity Date: 23-07-2031

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-089

Mehmet IŞIKLAR
General Manager

This certificate can be validated by scanning the QR code or entering necessary information at https://public.szutest-germany.de/

SZUTEST
Konformitätsbewertungsstelle GmbH

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

According to Annex IX-Chapters I and III of the Regulation (EU) 2017/745 on Medical Devices

Certificate No.: 2975-MED-2620502

Manufacturer:	**MEDİSOLARİS SAĞLIK HİZMETLERİ SAN. VE TİC. LTD. ŞTİ.** Fatih Mahallesi 1191. Sokak No:28/1 B Blok Gaziemir, İzmir, Türkiye
Manufacturer's SRN:	TR-MF-000015946
Device Information:	**See Section 2**
Report No.:	MD0018-P001-R01
Specific Conditions or Limitations:	N/A
Revision History:	**See Section 3**

SZUTEST Konformitätsbewertungsstelle GmbH, Notified Body 2975, declares that the aforementioned manufacturer has implemented a quality management system according to Annex IX Chapters I and III of the Regulation (EU) 2017/745 on medical devices. This quality system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Regulation. The approved quality system is subject to surveillance pursuant to Annex IX Chapter I Section 3 of the Regulation and unannounced site audits.

The Report(s) stated above summarize the conformity assessment results and include references to the relevant CS, harmonized standards, sampled/reviewed technical documentation, and test reports.

SZUTEST Konformitätsbewertungsstelle GmbH must be informed of any substantial changes in the design and/or construction of the mentioned device(s).

The quality management system evaluation is restricted,
For Class I devices in sterile conditions, to the aspects of manufacture concerned with securing and maintaining sterile conditions,
For Class I devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with metrological requirements
For Class I reusable surgical instruments, to the aspects of cleaning, disinfection, sterilization, maintenance and functional testing.
For Sterile Systems or Sterile Procedure Packs, to aspects of the sterilization procedure for ensuring sterility until the sterile package is opened or damaged.

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