ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 121445 0005 Rev. 00

Manufacturer:

Mais India Medical Devices Pvt. Ltd.
525P, Sector-37
Pace City II
Gurgaon, Haryana 122001
INDIA

SRN Manufacturer - IN-MF-000021842

Authorized Representative:

Obelis s.a.
Bd. Général Wahis 53, 1030 Brussels, BELGIUM

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 121445 0005 Rev. 00

Report No.: TPS1977
Valid from: 2025-06-04
Valid until: 2030-06-03

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-06-04

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Certificate No. G15 121445 0005 Rev. 00

Classification:	Class I
Device Group:	A03 - TUBULAR DEVICES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A07 - ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class IIa
Device Group:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
Classification:	Class IIa
Device Group:	MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
The validity of this certificate depends on conditions and/or is limited to the following:	-

Rev.	Dated	Report	Description
00	2025-06-04	TPS1977	Initial issuance

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