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 (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 107353 0004 Rev. 00

Manufacturer:

Harsoria Healthcare Pvt. Ltd
110-111 Udyog Vihar Phase-4
Gurgaon, Haryana 122015
INDIA

SRN Manufacturer - IN-MF-000018349

Authorized Representative:

Mdi Europa GmbH
Langenhagener Str. 71, 30855 Langenhagen, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 107353 0004 Rev. 00

Report No.: TPS0882
Valid from: 2024-03-13
Valid until: 2029-03-12

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-03-13

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class IIa
Device Group:	A01020302 - CUTANEOUS BIOPSY PUNCHES, SINGLE-USE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A010401 - ARTERIOVENOUS FISTULA NEEDLES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A030104 - FLOW REGULATORS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03020101 - LOW PRESSURE EXTENSION LINES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03020102 - HIGH PRESSURE EXTENSION LINES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A03010101 - INFUSION CONTROLLERS WITH OR W/O AIR INLET
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A0703 - STOPCOCKS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A070502 - CAPS OR OBTURATORS, PERFORABLE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	C0101010101 - PERIPHERAL I.V. CATHETERS, W/O SAFETY

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	SYSTEMS, WITH INJECTION VALVES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	C0101010102 - PERIPHERAL I.V. CATHETERS, W/O SAFETY SYSTEMS, W/O INJECTION VALVES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	C0101010201 - PERIPHERAL I.V. CATHETERS, WITH SAFETY SYSTEMS, WITH INJECTION VALVES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	C0101010202 - PERIPHERAL I.V. CATHETERS, WITH SAFETY SYSTEMS, W/O INJECTION VALVES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F900201 - TEMPORARY HEMODIALYSIS CATHETERS AND KITS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R01030101 - ENDOTRACHEAL TUBES, CUFFLESS, NOT REINFORCED
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R01030201 - ENDOTRACHEAL TUBES, CUFFED, NOT REINFORCED
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R01030202 - ENDOTRACHEAL TUBES, CUFFED, REINFORCED
Intended Purpose:	-
Classification:	Class IIa
Device Group:	R03010301 - AEROSOL THERAPY MASKS
Intended Purpose:	-

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No. G10 107353 0004 Rev. 00

Classification:	Class IIa
Device Group:	R9004 - PLEURAL TALCAGE DEVICES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	W0501010180 - VENOUS OR ARTERIOUS BLOOD COLLECTION DEVICES - ACCESSORIES
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2024-03-13	TPS0882	Initial issuance

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