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

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class IIa Devices)

No. G20 086097 0016 Rev. 01

Manufacturer:

Hangzhou Rollmed Co., Ltd.
Room 913, Yuanmao Mansion
No.5 Wen Er West Road
Xihu District
310012 Hangzhou City
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000016032

Authorized Representative:

MedNet EC-REP GmbH
Borkstraße 10, 48163 Münster, 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. The Notified Body confirms that the class IIa devices in question conform to the technical documentation and meet the requirements of this Regulation which apply to them. 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 XI Part A 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 assurance 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:G20 086097 0016 Rev. 01

Report No.: SH2378604

Preceding Certificate No.: G20 086097 0016 Rev. 00

Valid from: 2025-07-14
Valid until: 2029-03-19

Date of Initial Issuance: 2024-03-20

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-07-14

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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TÜV SÜD Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class IIa Devices)

No. G20 086097 0016 Rev. 01

Classification:	Class IIa
Device Group:	A060101 - VACUUM AND GRAVITY DRAINAGE SYSTEMS
Classification:	Class IIa
Device Group:	G020201 - NASOGASTRIC INTESTINAL TUBES
Classification:	Class IIa
Device Group:	G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHER
Classification:	Class IIa
Device Group:	R010301 - ENDOTRACHEAL TUBES, CUFFLESS
Classification:	Class IIa
Device Group:	R010302 - ENDOTRACHEAL TUBES, CUFFED
Classification:	Class IIa
Device Group:	R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS
Classification:	Class IIa
Device Group:	R030103 - AEROSOL THERAPY MASKS AND SYSTEMS
Classification:	Class IIa
Device Group:	R050101 - RESPIRATORY SUCTION PROBES
Classification:	Class IIa
Device Group:	R060202 - OXYGEN ADMINISTRATION HUMIDIFICATION SYSTEMS
Classification:	Class IIa
Device Group:	R050103 - MUCOUS ASPIRATORS
Classification:	Class IIa
Device Group:	A010101 - HYPODERMIC NEEDLES
Classification:	Class IIa
Device Group:	A010105 - NEEDLES FOR COLLECTION UNDER VACUUM

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EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class IIa Devices)

No. G20 086097 0016 Rev. 01

Classification:	Class IIa
Device Group:	A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
Classification:	Class IIa
Device Group:	A020106 - INSULIN SYRINGES, SINGLE-USE
Classification:	Class IIa
Device Group:	A030101 - INFUSION CONTROLLERS
Classification:	Class IIa
Device Group:	M020101 - COTTON GAUZES, CUT
Classification:	Class IIa
Device Group:	M020102 - COTTON GAUZES, FOLDED
Classification:	Class IIa
Device Group:	M020103 - LAPAROTOMY COTTON GAUZES
Classification:	Class IIa
Device Group:	R010201 - LARYNGEAL MASKS
Classification:	Class IIa
Device Group:	R010380 - ENDOTRACHEAL TUBES - ACCESSORIES
Classification:	Class IIa
Device Group:	R010502 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED
Classification:	Class IIa
Device Group:	R030199 - RESPIRATORY MASKS - OTHER
Classification:	Class IIa
Device Group:	R050102 - CLOSED-CIRCUIT RESPIRATORY SUCTION AND IRRIGATION SYSTEMS (NON-ENDOSCOPIC)

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Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class IIa Devices)

No. G20 086097 0016 Rev. 01

Classification:	Class IIa
Device Group:	R060101 - COLD NEBULISATION SYSTEMS
Classification:	Class IIa
Device Group:	R9099 - RESPIRATORY AND ANAESTHESIA DEVICES - OTHER
Classification:	Class IIa
Device Group:	U010105 - URETHRAL PROSTATIC AND BLADDER CATHETERS, NELATON
Classification:	Class IIa
Device Group:	U010106 - URETHRAL PROSTATIC AND BLADDER CATHETERS, TIEMANN
Classification:	Class IIa
Device Group:	U020202 - URETERAL CATHETERS WITH FLUTE TIP WITH BALLOON
Classification:	Class IIa
Device Group:	V010101 - SCALPELS WITH SAFETY SYSTEMS, SINGLE-USE
Classification:	Class IIa
Device Group:	V010302 - BLADES WITHOUT SAFETY SYSTEMS, SINGLE-USE - NOT INCLUDED IN OTHER CLASSES
Classification:	Class IIa
Device Group:	V010401 - LANCETS WITH SAFETY SYSTEMS, SINGLE-USE

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EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class IIa Devices)

No. G20 086097 0016 Rev. 01

Classification:	Class IIa
Device Group:	V010402 - LANCETS WITHOUT SAFETY SYSTEMS, SINGLE-USE
The validity of this certificate depends on conditions and/or is limited to the following:	N.A.

Revision History:

Rev.	Dated	Report	Description
00	2024-03-20	SH2378601	Initial issuance
01	2025-07-14	SH2378604	Supplemented: Device(s)/group of device(s) added

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