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 I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 071789 0050 Rev. 01

Manufacturer:

Conod Medical Co., Limited
No. 11 Hongfeng Road
Baimao Industrial Park, Guli Town
215532 Changshu City, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000012600

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, 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. As applicable the involvement of the notified body is limited to the 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.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH.
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:G11 071789 0050 Rev. 01

Report No.: SH2450402

Preceding Certificate No.: G11 071789 0050 Rev. 00

Valid from: 2024-09-06
Valid until: 2027-10-16

Date of Initial Issuance: 2022-10-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-06

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 I
Device Group:	A060303 - URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A02010203 - INFUSION AND IRRIGATION SYRINGES, CATHETER CONE, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A02010701 - PREFILLED SYRINGES WITH STERILE PHYSIOLOGICAL SOLUTION
Device Properties:	MDS 1005.2 - Sterilisation by irradiation
Classification:	Class I
Device Group:	A02010702 - PREFILLED SYRINGES WITH STERILE WATER
Device Properties:	MDS 1005.2 - Sterilisation by irradiation
Classification:	Class I
Device Group:	A03010301 - ENTERAL FEEDING GRAVITY CONTROLLERS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A0601010102 - DRAINAGE SYSTEMS WITH RESERVOIR
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A0601010103 - BELLOWS DRAINAGE SYSTEMS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A060102 - SURGICAL DRAINAGE CONNECTION MEDICAL TUBES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A060201 - EXTERNAL DRAINAGE CATHETERS AND KITS (ABSCESSES, GALLSTONES, CYSTS)
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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No. G11 071789 0050 Rev. 01

Classification:	Class I
Device Group:	A060204 - THORACENTESIS AND PARACENTESIS DRAINAGES AND KITS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A060206 - PERITONAEAL DRAINAGES AND KITS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	U01010502 - NELATON CATHETERS, NON SELF-LUBRICATING
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	G020101 - GASTRIC LAVAGE TUBES AND SETS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	G020102 - INTESTINAL LAVAGE TUBES AND SETS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	V0599 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	V9012 - NON-SPECIALIST SURGICAL INSTRUMENTS AND KITS, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A06030301 - URINE COLLECTION BAGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization
Classification:	Class I
Device Group:	A0703 - STOPCOCKS

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Device Properties: MDS 1005.1 - Ethylene Oxide sterilization

The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2022-10-17	SH21504MDR	-
01	2024-09-06	SH2450402	Supplemented: Device(s)/group of device(s) added

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