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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 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 071789 0049 Rev. 02

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.
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 071789 0049 Rev. 02

Report No.: SH2450402

Preceding Certificate No.: G10 071789 0049 Rev. 01

Valid from: 2024-11-25
Valid until: 2027-10-16
Date of Initial Issuance: 2022-10-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-11-25

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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No. G10 071789 0049 Rev. 02

Classification:	Class IIb
Device Group:	U010299 - URETHRAL PROSTATIC AND BLADDER CATHETERS, WITH BALLOON - OTHER
Intended Purpose:	The urethral catheter is a tubular device intended for being introduced into the vesical cavity through the urethra in order to provide drainage and/or flushing of the bladder for adult patients, and drainage for pediatric patients. The continuous use for a single device is for no more than 29 days. The cumulative use for each type of urethral catheter can exceed 30 days.
Classification:	Class IIa
Device Group:	A0601010102 - DRAINAGE SYSTEMS WITH RESERVOIR
Intended Purpose:	na
Classification:	Class IIa
Device Group:	A0601010103 - BELLOWS DRAINAGE SYSTEMS
Intended Purpose:	na
Classification:	Class IIa
Device Group:	A06010103 - CANNULAS AND TIPS FOR ASPIRATION AND IRRIGATION, SINGLE-USE
Intended Purpose:	na
Classification:	Class IIa
Device Group:	A060102 - SURGICAL DRAINAGE CONNECTION MEDICAL TUBES
Intended Purpose:	na
Classification:	Class IIa
Device Group:	A080101 - ENTERAL FEEDING BAGS AND CONTAINERS (INCLUDING THOSE VIA PUMP), SINGLE-USE
Intended Purpose:	na
Classification:	Class IIa
Device Group:	G99 - GASTROINTESTINAL DEVICES - OTHER
Intended Purpose:	na
Classification:	Class IIa
Device Group:	V0599 - CLINICAL PROCEDURES KITS NOT INCLUDED IN OTHER CLASSES - OTHER
Intended Purpose:	na

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No. G10 071789 0049 Rev. 02

Classification:	Class IIa
Device Group:	V9007 - STERILE INSTRUMENT LUBRICANTS
Intended Purpose:	na
Classification:	Class IIa
Device Group:	U010299 - URETHRAL PROSTATIC AND BLADDER CATHETERS, WITH BALLOON - OTHER
Intended Purpose:	NA
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
02	2024-11-25	SH2450402	Supplemented: Device(s)/group of device(s) added

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