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

TÜV SÜD Product Service

EU Production Quality Assurance Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 069211 0028 Rev. 00

Manufacturer:

Hangzhou Bever Medical Devices Co., Ltd.
Building 2, No. 1-1, Houmuqiao
Yongle Village, Cangqian Street
Yuhang District
311121 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000018408

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex XI Part A 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 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 devices conform to the technical documentation. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class IIb or class III devices are covered by this certificate, the quality management system ensures that devices conform to the type that has undergone a type examination. An EU Type-Examination Certificate in accordance with Annex X 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:G26 069211 0028 Rev. 00

Report No.: SH2354403
Valid from: 2025-07-30
Valid until: 2030-07-29

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-07-30

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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Product Service

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Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A

Certificate No. G26 069211 0028 Rev. 00

Classification:	Class I
Device Group:	R010101 - NASOPHARYNGEAL TUBES U01010501 - NELATON CATHETERS, SELF-LUBRICATING U01010502 - NELATON CATHETERS, NON SELF-LUBRICATING U01010601 - TIEMANN CATHETERS, SELF-LUBRICATING U01010602 - TIEMANN CATHETERS, NON SELF-LUBRICATING U03010201 - URETHRAL DILATORS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class IIa
Device Group:	MDN 1201 - Non-active non-implantable devices for anaesthesia, emergency and intensive care
Intended Purpose:	The suction catheter is used for aspiration of physiological secretions from throat, nose or trachea on adults or children.
The validity of this certificate depends on conditions and/or is limited to the following:	NA

Revision History:

Rev.	Dated	Report	Description
00	2025-07-30	SH2354403	Initial issuance

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