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 061585 0036 Rev. 03

Manufacturer:

B. Braun Medical AG
Seesatz 17
6204 Sempach
SWITZERLAND

SRN Manufacturer - CH-MF-000017781

Authorized Representative:

B. Braun Melsungen AG
Carl-Braun-Str. 1, 34212 Melsungen, 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 061585 0036 Rev. 03

Report No.: 713255484

Preceding Certificate No.: G10 061585 0036 Rev. 02

Valid from: 2024-08-13
Valid until: 2026-03-14

Date of Initial Issuance: 2021-03-15

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-08-13

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:	D02010102 - CHLORHEXIDINE, HYDROALCOHOLIC SOLUTION FOR THE DISINFECTION OF MEDICAL DEVICES
Intended Purpose:	Soaked wipes for surface disinfection of non-invasive medical devices

Classification:	Class IIa
Device Group:	D0701 - ETHANOL FOR THE DISINFECTION OF MEDICAL DEVICES
Intended Purpose:	Solutions for surface disinfection of non- invasive medical devices

Classification:	Class IIa
Device Group:	D0799 - ALCOHOLS FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER
Intended Purpose:	Surface disinfection of non-invasive medical devices.

Classification:	Class IIa
Device Group:	D0901 - AMMONIUM SALTS FOR THE DISINFECTION OF MEDICAL DEVICES
Intended Purpose:	Cleaner and Disinfectant for the mechanical reprocessing of non-invasive medical devices e.g. bedsteads, mattresses, containers, transport carts, OR tables, OR accessories, wheelchairs, OR shoes, bedside furniture

Classification:	Class IIa
Device Group:	D0901 - AMMONIUM SALTS FOR THE DISINFECTION OF MEDICAL DEVICES
Intended Purpose:	Surface disinfection of non-invasive medical devices.

Classification:	Class IIb
Device Group:	D01010102 - GLUTARALDEHYDE, ACIDIC SOLUTION FOR THE DISINFECTION OF MEDICAL DEVICES
Intended Purpose:	Disinfectant for the mechanical reprocessing of medical devices / flexible endoscopes.

Classification:	Class IIb
Device Group:	D01010102 - GLUTARALDEHYDE, ACIDIC SOLUTION FOR THE DISINFECTION OF MEDICAL DEVICES
Intended Purpose:	Instrument disinfectant for manual processing of surgical instruments, endoscopes incl. flexible endoscopes.

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No. G10 061585 0036 Rev. 03

Classification:	Class IIa
Device Group:	U0180 - URETHRAL PROSTATIC AND BLADDER CATHETERS - ACCESSORIES
Intended Purpose:	Sterile urinary catheter irrigation solutions
Classification:	Class IIa
Device Group:	D0902 - ASSOCIATED AMMONIUM SALTS FOR THE DISINFECTION OF MEDICAL DEVICES
Intended Purpose:	Solution for instrument disinfection of dental and surgical instruments and invasive medical devices prior to sterilization
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2021-03-15	713183172	-
01	2023-04-24	713264897	- Supplemented: Change to the approved type(s)/device(s)
02	2024-03-20	713209669	Supplemented: Device(s)/group of device(s) added
03	2024-08-13	713255484	Supplemented: Device(s)/group of device(s) added

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