



## 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. 02**

### 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. 02](http://www.tuvsud.com/ps-cert?q=cert:G10 061585 0036 Rev. 02)

**Report No.:** 713209669

**Preceding Certificate No.:** G10 061585 0036 Rev. 01

**Valid from:** 2024-03-20

**Valid until:** 2026-03-14

**Date of Initial Issuance:** 2021-03-15

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2024-03-20



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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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**Classification:** Class IIa  
**Device Group:** U0180 - URETHRAL PROSTATIC AND BLADDER CATHETERS - ACCESSORIES  
**Intended Purpose:** Sterile urinary catheter irrigation solutions

**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	-
02	2024-03-20	713209669	Supplemented: Change to the approved type(s)/device(s) Supplemented: Device(s)/group of device(s) added