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 Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 061585 0043 Rev. 00

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 quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I 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 or class IIb 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 periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III (excluding custom-made implantable devices) or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II 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:G15 061585 0043 Rev. 00

Report No.:	713380473 / 713380611
Preceding Certificate No.:	G10 061585 0036 Rev. 04 G11 061585 0037 Rev. 01
Valid from:	2026-03-15
Valid until:	2031-03-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-02-03

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Certificate No. G15 061585 0043 Rev. 00

Classification:	Class I
Device Group:	M040499 - DRESSINGS FOR WOUNDS, SORES AND ULCERATIONS - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	V9099 - VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES - OTHER
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class IIa
Device Group:	MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing
Intended Purpose:	Soaked wipes for surface disinfection of non-invasive medical devices
Classification:	Class IIa
Device Group:	MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing
Intended Purpose:	Solutions for surface disinfection of non- invasive medical devices
Classification:	Class IIa
Device Group:	MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing
Intended Purpose:	Surface disinfection of non-invasive medical devices.
Classification:	Class IIa
Device Group:	MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing
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:	MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing
Intended Purpose:	Solution for instrument disinfection of dental and surgical instruments and invasive medical devices prior to sterilization
Classification:	Class IIa
Device Group:	MDN 1213 - Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route
Intended Purpose:	Sterile urinary catheter irrigation solutions
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.

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EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 061585 0043 Rev. 00

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.
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2026-03-15	713380473 / 713380611	Administrative merge / transfer to new Certificate Type

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