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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

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

Certificate No. G15 044904 0059 Rev. 00

Manufacturer:

B. Braun Medical Inc.
824 Twelfth Avenue
Bethlehem PA 18018
USA

SRN Manufacturer - US-MF-000011193

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 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 044904 0059 Rev. 00

Report No.:	721011098
Preceding Certificate No.:	G10 044904 0057 Rev. 00 G11 044904 0056 Rev. 00
Valid from:	2025-08-29
Valid until:	2027-09-22

Issue date: 2025-08-29

Christoph Dicks
Head of Certification/Notified Body

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Classification:	Class IIa
Device Group:	MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
Classification:	Class IIa
Device Group:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
Classification:	Class I
Device Group:	C01 - ARTERIO-VENOUS SYSTEM DEVICES
Device Properties:	MDS 1005 - Devices in sterile condition MDS 1010 - Devices with a measuring function
Classification:	Class I
Device Group:	A03 - TUBULAR DEVICES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A07 - ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS
Device Properties:	MDS 1005 - Devices in sterile condition
The validity of this certificate depends on conditions and/or is limited to the following:	-

Revision History:

Rev.	Dated	Report	Description
00	2025-08-29	721011098	Supplemented: Device(s)/group of device(s) added Administrative merge / transfer to new Certificate Type

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