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

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

Certificate No. G15 019717 0043 Rev. 00

Manufacturer: **B. Braun Avitum Italy S.p.A.**
Via XXV Luglio, 11
41037 Mirandola (MO)
ITALY

SRN Manufacturer - IT-MF-000010730

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 019717 0043 Rev. 00

Report No.:	713354948
Preceding Certificate No.:	G10 019717 0034 Rev. 01 G11 019717 0035 Rev. 02 G12 019717 0039 Rev. 01
Valid from:	2025-11-16
Valid until:	2030-11-15

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-07-01

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Certificate No. G15 019717 0043 Rev. 00

Classification:	Class I
Device Group:	A03 - TUBULAR DEVICES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A06 - DRAINAGE AND FLUIDS COLLECTION DEVICES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A08 - NUTRITION AND INFUSION BAGS AND CONTAINERS, SINGLE-USE
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	U01 - URETHRAL, PROSTATIC AND BLADDER CATHETERS
Device Properties:	MDS 1005 - Devices in sterile condition
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 IIa
Device Group:	MDN 1214 - General non-active non-implantable devices used in health care and other non-active non-implantable devices
Classification:	Class IIb Implantable
Device Group:	MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
Intended Purpose:	See product certificate
Classification:	Class III
Device Group:	MDN 1204 - Non-active non-implantable devices for wound and skin care
Intended Purpose:	See product certificate
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description	
00	2025-11-16	713354948	Renewal of certificate	Administrative merge/transfer to new Certificate Type

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