



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 019717 0035 Rev. 02

Manufacturer:

B. Braun Avitum Italy S.p.A.

Via XXV Luglio, 11
41037 Mirandola (MO)
ITALY

SRN Manufacturer - IT-MF-000010730

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. As applicable the involvement of the notified body is limited to the 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.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 019717 0035 Rev. 02

Report No.: 713266951

Preceding Certificate No.: G11 019717 0035 Rev. 01

Valid from: 2023-06-22

Valid until: 2025-11-15

Date of Initial Issuance: 2020-11-16

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-06-22



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Classification: Class I
Device Group: A03 - TUBULAR DEVICES
A06 - DRAINAGE AND FLUIDS COLLECTION DEVICES
A08 - NUTRITION AND INFUSION BAGS AND CONTAINERS,
SINGLE-USE
U01 - URETHRAL, PROSTATIC AND BLADDER CATHETERS
Device Properties: MDS 1005.1 - Ethylene Oxide sterilization

Classification: Class I
Device Group: U01 - URETHRAL, PROSTATIC AND BLADDER CATHETERS
Device Properties: MDS 1005.2 - Sterilisation by irradiation

The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2020-11-16	713175105	-
01	2020-11-17	713175105	-
02	2023-06-22	713266951	-
Supplemented: Other			