



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Implantable Class IIb Devices and Class III Devices)

No. G12 019717 0039 Rev. 01

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.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. 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:G12 019717 0039 Rev. 01

Report No.: 713262022

Preceding Certificate No.: G12 019717 0039 Rev. 00

Valid from: 2024-06-26

Valid until: 2025-11-15

Date of Initial Issuance: 2024-01-12

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-06-26



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Classification: Class IIb
Device Group: F900101 - PERITONEAL DIALYSIS CATHETERS AND KITS
Intended Purpose: -

Classification: Class III
Device Group: M040408 - SILVER DRESSINGS
Intended Purpose: -

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

Revision History:

Rev.	Dated	Report	Description
00	2024-01-12	713250934	Initial issuance
01	2024-06-26	713262022	Supplemented: Device(s)/group of device(s) added