ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD
Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 12 19717 026

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

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

Product Category(ies):

Sterile Medical Disposables:
Containers, administration sets and accessories for solutions

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Lines and accessories for hemodialysis, peritoneal dialysis and plasma treatment

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Lines, containers and accessories for infusion, collection and administration of drugs, perfusional and nutritional solutions

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Tubing system, filters and accessories for blood treatment

Catheters for peritoneal dialysis

Lines and accessories for irrigation, urology and arthroscopy

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Digitally signed by Dicusar Vladimir
Date: 2025.09.12 13:53:24 EEST
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Valid from: 2015-06-23
Valid until: 2020-06-22

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Date, 2015-03-16

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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