Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 019717 0032 Rev. 00

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.

Report No.: 713159695

Valid from: 2019-12-03
Valid until: 2024-05-26

Date, 2019-12-03

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany