



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

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 019717 0033 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):

**Containers for Solutions;
Accessories for Dialysis, Nutrition, Infusion
and Apheresis;
Sets for Infusion and Irrigation**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

713168203

Valid from:

2019-12-02

Valid until:

2024-05-26

Date,

2019-12-02

Christoph Dicks
Head of Certification/Notified Body