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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 066097 0096 Rev. 02

Manufacturer:

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
GERMANY

Product Category(ies):

Active and non-active medical devices for extracorporeal blood treatments:
- Active medical devices for extracorporeal blood treatment: hemodialysis, acute dialysis, plasmapheresis.
Reverse osmosis Systems, central concentrate supply Systems, ring piping and hot disinfection Systems for dialysis;
- Kit for Dialysis and Haemo(dia)filtration (extracorporeal Circuit and dialyser); Lines for Dialysis and Haemo(dia)filtration;
- Kit for Plasma Treatment (Extracorporeal Circuit and Plasma filter); Lines for Plasma Treatment;
-Dialyzers, hemofilters, hemodiafilters, dialysis fluid filters, hemofilters for continuous renal replacement therapy;
- Plasma Filter Haemoselect;
- Blood filtration devices; H.E.L.P. SYSTEM kit;
- S.A.F.E. Apheresis Set;
- A.V. Fistula needles
- Catheters and Catheter Sets for Dialysis;
- Disinfectants for Dialysis Machines;
- Sterile and non-sterile hemodialysis concentrates (class IIb), solid dosage form for hemodialysis (class IIb) and irrigation Solutions (class IIa)

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.: 713168200

Valid from: 2020-02-28
Valid until: 2024-05-26

Digitally signed by Moraru Grigore
Date: 2024.01.12 17:46:13 EET
Reason: MoldSign Signature
Location: Moldova

Date, 2020-02-28

Christoph Dicks
Head of Certification/Notified Body

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

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Product Service

Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 066097 0103 Rev. 00

Manufacturer:

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
GERMANY

This List of Sites is only valid in combination with the following EC Certificate (MDD): **G1 066097 0096 Rev. 02**

The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EC Certificate pursuant to the Directive 93/42/EEC (MDD) concerning medical devices.

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MÜNCHEN TÜV SÜD PRODUCT SERVICE

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Product Service

Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 066097 0103 Rev. 00

Sites:

B. Braun Avitum AG
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

B. Braun Avitum AG, Werk Glandorf
Kattenvenner Straße 32, 49219 Glandorf, GERMANY

B. Braun Avitum Saxonia GmbH
Juri-Gagarin-Strasse 13, 01454 Radeberg, GERMANY

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

B. Braun Avitum AG
Am Buschberg 1, 34212 Melsungen, GERMANY

B. Braun Melsungen AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

Lauer Membran Wassertechnik GmbH
Speichermatt 9, 79599 Wittlingen, GERMANY

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