



Certificate

No. Q5 066097 0091 Rev. 05

Holder of Certificate:



B. Braun Avitum AG

Schwarzenberger Weg 73-79
34212 Melsungen
GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Production, Distribution, Installation, and Servicing of Active Medical Devices for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis) and for Water Treatment and Supply Systems;
Design and Development, Production and Distribution of Non-Active Sterile and Non-Sterile Medical Devices for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis);
Provision of Services for Design and Development, Production, Installation, and Servicing for General Active Medical Devices;
Provision of Design and Development and Production Services for General Non-Active, Non-Implantable Medical Devices;
Importation and Distribution of Non-Active Medical Devices;
Distribution of Active Medical Devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5_066097_0091_Rev.05

Report No.: 713315544

Valid from: 2024-08-01

Valid until: 2027-07-31

Date, 2024-07-25



Christoph Dicks

Head of Certification/Notified Body

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **B. Braun Avitum AG**
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

Production of Active Medical Devices for Water Treatment and Supply Systems;
Production of Parts and Components for General Active Medical Devices;
Servicing for General Active Medical Devices.

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

Design and Development, Production, Distribution, Installation, and Servicing of Active Medical Devices for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis) and Active Medical Devices for Water Treatment and Supply Systems;
Design and Development, Production, and Installation of General Active Medical Devices;
Importation and Distribution of Non-Active Medical Devices;
Distribution of Active Medical Devices.

B. Braun Avitum AG
Dörnbach 22, 34286 Spangenberg, GERMANY

Production of Parts and Components for General Active Medical Devices

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

Design and Development, and Production of Sterile and Non-Sterile Fluids and Concentrates for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis);
Distribution of Non-Active Medical Devices

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

Design and Development, Production and Distribution of Non-Active Sterile and Non-Sterile Medical Devices for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis);
Distribution and Servicing of Active Non-Sterile Medical Devices for Extracorporeal Blood Treatment;
Production of Components for General Active Medical Devices.

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B. Braun Avitum Saxonia GmbH

Juri-Gagarin-Strasse 13, 01454 Radeberg, GERMANY

Design and Development, and Production of Sterile and Non-Sterile Non-Active Medical Devices (Dialyzers and Filters) for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis).

B. Braun Avitum Saxonia GmbH Werk Obernburg

Glanzstoffstr. 1, 63820 Elsenfeld, GERMANY

Design and Development, and Production of Non-Active Medical Devices for Extracorporeal Blood Treatment (Apheresis) and Water Treatment.

B. Braun Avitum Saxonia GmbH

Oberer Ladenberg 18, 01816 Bad Gottleuba-Berggießhübel, GERMANY

Production of Hollow Fiber Membranes for the Use in Non-Active Medical Devices (Dialyzers and Filters) for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis).

B. Braun Avitum Saxonia GmbH

Dresdner Tor 5, 01723 Wilsdruff, GERMANY

Production of Non-Active Medical Devices (Dialyzers and Filters) for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis).