ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 066097 0125 Rev. 00

Manufacturer:

B BRAUN
SHARING EXPERTISE

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

SRN Manufacturer - DE-MF-000005127

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 066097 0125 Rev. 00

Report No.:	713354956
Preceding Certificate No.:	G10 066097 0106 Rev. 05 G11 066097 0107 Rev. 02 G12 066097 0118 Rev. 00 GRS 066097 0113 Rev. 03
Valid from:	2025-10-02
Valid until:	2030-10-01

Issue date: 2025-09-02

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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 066097 0125 Rev. 00

Classification:	Class I
Device Group:	F02 - DIALYSIS LINES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	F04 - DIALYSIS CONCENTRATES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	F90 - DIALYSIS DEVICES - VARIOUS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class IIa
Device Group:	MDA 0306 - Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis
Classification:	Class IIa
Device Group:	MDA 0315 - Software
Classification:	Class IIa
Device Group:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
Classification:	Class IIb
Device Group:	B030201 - PLASMAPHERESIS DEVICES AND KITS
Intended Purpose:	Apheresis set.
Classification:	Class IIb
Device Group:	D99 - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES - OTHER
Intended Purpose:	Liquid concentrate for the cleaning, decalcification and heat-disinfection of the fluid pathway of hemodialysis machines.
Classification:	Class IIb
Device Group:	F010601 - DIALYSERS - UFC < 18 ml/h/mmHg
Intended Purpose:	Dialyzers to be used in hemodialysis and hemo(dia)filtration.
Classification:	Class IIb
Device Group:	F010603 - DIALYSERS - UFC > 35 ml/h/mmHg
Intended Purpose:	Dialyzers to be used in hemodialysis and hemo(dia)filtration.
Classification:	Class IIb
Device Group:	F0306 - CONTINUOUS DIALYSIS KITS
Intended Purpose:	Set consisting of extracorporeal circuits and filter for continuous blood purification treatment.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 066097 0125 Rev. 00

Classification:	Class IIb
Device Group:	F040101 - DIALYSIS CONCENTRATES, ACID SOLUTIONS, NON-STERILE
Intended Purpose:	Acidic concentrate for bicarbonate hemodialysis or hemodiafiltration.
Classification:	Class IIb
Device Group:	F040201 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, POWDER
Intended Purpose:	Alkaline concentrates to be used in bicarbonate hemodialysis or hemodiafiltration.
Classification:	Class IIb
Device Group:	F040202 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, LIQUID
Intended Purpose:	Alkaline concentrates to be used in bicarbonate hemodialysis or hemodiafiltration.
Classification:	Class IIb
Device Group:	F0499 - DIALYSIS CONCENTRATES - OTHER
Intended Purpose:	Ready-to-use solution for extracorporeal blood treatment.
Classification:	Class IIb
Device Group:	Z120902 - HAEMODIALYSIS INSTRUMENTS
Intended Purpose:	Equipment for extracorporeal blood treatments to administer and remove substances and body fluids.
Classification:	Class IIb
Device Group:	Z120990 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS INSTRUMENTS
Intended Purpose:	Production of water for diluting hemodialysis concentrates.
Classification:	Class III
Device Group:	MDN 1202 - Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
Intended Purpose:	See product certificate
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2025-10-02	713354956	Renewal of certificate

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®