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www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Manufacturer:

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

SRN Manufacturer - DE-MF-000005127

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 066097 0106 Rev. 03

Report No.: 713258363_G10change

Preceding Certificate No.: G10 066097 0106 Rev. 02

Valid from: 2023-11-23
Valid until: 2025-10-01

Date of Initial Issuance: 2021-06-16

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-11-23

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

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(Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

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:	D99 - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES - OTHER
Intended Purpose:	Liquid concentrates for the cleaning, decalcification and heat-disinfection of the fluid pathways of hemodialysis machines

Classification:	Class IIb
Device Group:	Z120990 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS INSTRUMENTS
Intended Purpose:	Production of water for diluting hemodialysis concentrates

Classification:	Class IIb
Device Group:	F0499 - DIALYSIS CONCENTRATES - OTHER
Intended Purpose:	Ready-to-use solution for extracorporeal blood treatment

Classification:	Class IIb
Device Group:	F0306 - CONTINUOUS DIALYSIS KITS
Intended Purpose:	Sets consisting of extracorporeal circuits and filters for continuous blood purification treatment

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:	F010601 - DIALYSERS - UFC < 18 ml/h/mmHg
Intended Purpose:	Dialyzers to be used in hemodialysis and hemo(dia)filtration

Classification:	Class IIb
Device Group:	F010602 - DIALYSERS - UFC = 18 - 35 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

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No. G10 066097 0106 Rev. 03

Intended Purpose:	Dialyzers to be used in hemodialysis and hemo(dia)filtration
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:	F040202 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, LIQUID
Intended Purpose:	Alkaline concentrates to be used in bicarbonate hemodialysis or hemodiafiltration
Classification:	Class IIb
Device Group:	B030201 - PLASMAPHERESIS DEVICES AND KITS
Intended Purpose:	Apheresis set
Classification:	Class IIa
Device Group:	F020102 - ARTERIOVENOUS DIALYSIS LINES, TWO NEEDLES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F020104 - REINFUSION DIALYSIS LINES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F020199 - ARTERIOVENOUS DIALYSIS LINES FOR HAEMODIALYSIS - HAEMOFILTRATION - HAEMODIAFILTRATION - OTHER
Intended Purpose:	-
Classification:	Class IIa
Device Group:	B030201 - PLASMAPHERESIS DEVICES AND KITS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F900301 - HAEMODIALYSIS ADAPTORS
Intended Purpose:	-

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Classification: Class IIa
Device Group: A010401 - ARTERIOVENOUS FISTULA NEEDLES
Intended Purpose: -

Classification: Class IIa
Device Group: C010280 - CENTRAL VENOUS CATHETERS - ACCESSORIES
Intended Purpose: -

Classification: Class IIa
Device Group: F0305 - HAEMOPERFUSION KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F0301 - HAEMOFILTRATION-HAEMODIAFILTRATION KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F0303 - HAEMODIALYSIS KITS
Intended Purpose: -

Classification: Class IIa
Device Group: B0380 - APHERESIS DEVICES - ACCESSORIES
Intended Purpose: -

Classification: Class IIa
Device Group: F0306 - CONTINUOUS DIALYSIS KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F0307 - ULTRAFILTRATION KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F020180 - ARTERIOVENOUS DIALYSIS LINES FOR HAEMODIALYSIS - HAEMOFILTRATION - HAEMODIAFILTRATION - ACCESSORIES
Intended Purpose: -

Classification: Class IIa

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Device Group: A010499 - DIALYSIS NEEDLES - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: B030299 - APHERESIS THERAPY DEVICES - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: B0399 - APHERESIS DEVICES - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: F020101 - ARTERIOVENOUS DIALYSIS LINES, ONE NEEDLE
Intended Purpose: -

Classification: Class IIa
Device Group: F0199 - HAEMODIALYSIS FILTERS - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: Z120990 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS INSTRUMENTS
Intended Purpose: -

The validity of this certificate depends on conditions and/or is limited to the following: .None.

Revision History:

Rev.	Dated	Report	Description
00	2021-06-16	713175105	-
01	2022-03-03	713175105	-
02	2023-02-20	713221085_DIV_G10change	-
03	2023-11-23	713258363_G10change	Supplemented: Device(s)/group of device(s) added

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