



## 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](http://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



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|                          |  |
|--------------------------|--|
| <b>Classification:</b>   | Class IIb  |
| <b>Device Group:</b>     | Z120902 - HAEMODIALYSIS INSTRUMENTS  |
| <b>Intended Purpose:</b> | Equipment for extracorporeal blood treatments to administer and remove substances and body fluids                          |
| <b>Classification:</b>   | Class IIb  |
| <b>Device Group:</b>     | D99 - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES - OTHER                            |
| <b>Intended Purpose:</b> | Liquid concentrates for the cleaning, decalcification and heat-disinfection of the fluid pathways of hemodialysis machines |
| <b>Classification:</b>   | Class IIb  |
| <b>Device Group:</b>     | Z120990 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS INSTRUMENTS   |
| <b>Intended Purpose:</b> | Production of water for diluting hemodialysis concentrates   |
| <b>Classification:</b>   | Class IIb  |
| <b>Device Group:</b>     | F0499 - DIALYSIS CONCENTRATES - OTHER  |
| <b>Intended Purpose:</b> | Ready-to-use solution for extracorporeal blood treatment   |
| <b>Classification:</b>   | Class IIb  |
| <b>Device Group:</b>     | F0306 - CONTINUOUS DIALYSIS KITS   |
| <b>Intended Purpose:</b> | Sets consisting of extracorporeal circuits and filters for continuous blood purification treatment                         |
| <b>Classification:</b>   | Class IIb  |
| <b>Device Group:</b>     | F040201 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, POWDER   |
| <b>Intended Purpose:</b> | Alkaline concentrates to be used in bicarbonate hemodialysis or hemodiafiltration  |
| <b>Classification:</b>   | Class IIb  |
| <b>Device Group:</b>     | F010601 - DIALYSERS - UFC < 18 ml/h/mmHg   |
| <b>Intended Purpose:</b> | Dialyzers to be used in hemodialysis and hemo(dia)filtration   |
| <b>Classification:</b>   | Class IIb  |
| <b>Device Group:</b>     | F010602 - DIALYSERS - UFC = 18 - 35 ml/h/mmHg  |
| <b>Intended Purpose:</b> | Dialyzers to be used in hemodialysis and hemo(dia)filtration   |
| <b>Classification:</b>   | Class IIb  |
| <b>Device Group:</b>     | F010603 - DIALYSERS - UFC > 35 ml/h/mmHg   |



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|                          |   |
|--------------------------|---|
| <b>Intended Purpose:</b> | Dialyzers to be used in hemodialysis and hemo(dia)filtration  |
| <b>Classification:</b>   | Class IIb   |
| <b>Device Group:</b>     | F040101 - DIALYSIS CONCENTRATES, ACID SOLUTIONS, NON-STERILE  |
| <b>Intended Purpose:</b> | Acidic concentrate for bicarbonate hemodialysis or hemodiafiltration                                    |
| <b>Classification:</b>   | Class IIb   |
| <b>Device Group:</b>     | F040202 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, LIQUID  |
| <b>Intended Purpose:</b> | Alkaline concentrates to be used in bicarbonate hemodialysis or hemodiafiltration                       |
| <b>Classification:</b>   | Class IIb   |
| <b>Device Group:</b>     | B030201 - PLASMAPHERESIS DEVICES AND KITS   |
| <b>Intended Purpose:</b> | Apheresis set   |
| <b>Classification:</b>   | Class IIa   |
| <b>Device Group:</b>     | F020102 - ARTERIOVENOUS DIALYSIS LINES, TWO NEEDLES   |
| <b>Intended Purpose:</b> | -   |
| <b>Classification:</b>   | Class IIa   |
| <b>Device Group:</b>     | F020104 - REINFUSION DIALYSIS LINES   |
| <b>Intended Purpose:</b> | -   |
| <b>Classification:</b>   | Class IIa   |
| <b>Device Group:</b>     | F020199 - ARTERIOVENOUS DIALYSIS LINES FOR HAEMODIALYSIS - HAEMOFILTRATION - HAEMODIAFILTRATION - OTHER |
| <b>Intended Purpose:</b> | -   |
| <b>Classification:</b>   | Class IIa   |
| <b>Device Group:</b>     | B030201 - PLASMAPHERESIS DEVICES AND KITS   |
| <b>Intended Purpose:</b> | -   |
| <b>Classification:</b>   | Class IIa   |
| <b>Device Group:</b>     | F900301 - HAEMODIALYSIS ADAPTORS  |
| <b>Intended Purpose:</b> | -   |



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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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### No. G10 066097 0106 Rev. 03

**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 |