CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

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

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 037258 0014 Rev. 06

Manufacturer:

Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY

SRN Manufacturer - DE-MF-000009273

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, 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:G10 037258 0014 Rev. 06

Report No.:	713315316
Preceding Certificate No.:	G10 037258 0014 Rev. 05
Valid from:	2026-06-22
Valid until:	2026-10-17
Date of Initial Issuance:	2021-10-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-06-22

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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Classification:	Class IIb
Device Group:	B020101 - BED-SIDE LEUKOREDUCTION FILTERS
Intended Purpose:	Filters are medical devices intended for leukocyte reduction of blood components for transfusion.

Classification:	Class IIb
Device Group:	Z121704 - APHERESIS EQUIPMENT
Intended Purpose:	Apheresis Devices intended for the collection of blood components. Apheresis Devices intended for the collection of blood components and/or therapeutic apheresis.

Classification:	Class IIb
Device Group:	B020102 - LABORATORY LEUKOREDUCTION FILTERS
Intended Purpose:	Filters are medical devices intended for leukocyte reduction of blood components for transfusion.

Classification:	Class IIa
Device Group:	Z121780 - BLOOD TRANSFUSION INSTRUMENTS - HARDWARE ACCESSORIES
Intended Purpose:	-/-

Classification:	Class IIb
Device Group:	B0401 - INTRA- AND POSTOPERATIVE BLOOD COLLECTION, WASHING AND REINFUSION DEVICES AND KITS
Intended Purpose:	Processing of autologous shed blood collected intra-operatively and postoperatively to obtain washed packed red blood cells for reinfusion or for peri-operative separation of blood into Packed Red Cells, Plasma and Platelet Rich Plasma.

Classification:	Class IIb
Device Group:	B030204 - EXTRACORPOREAL PHOTOCHEMOTHERAPY OR PHOTOPHERESIS DEVICES AND KITS
Intended Purpose:	Apheresis devices intended for the administration of Extracorporeal Photopheresis (ECP).

Classification:	Class IIb
Device Group:	B030202 - CYTAPHERESIS DEVICES AND KITS
Intended Purpose:	Apheresis Devices intended for the collection of blood components. Apheresis devices intended for the collection of blood components and/or therapeutic apheresis

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Classification:	Class IIb
Device Group:	B030201 - PLASMAPHERESIS DEVICES AND KITS
Intended Purpose:	Apheresis devices intended for the collection of blood components.

Classification:	Class IIb
Device Group:	B010299 - BLOOD TRANSFER BAGS AND KITS - OTHER
Intended Purpose:	Blood Transfer Bags are for the processing, filtration and/or storage of whole blood or blood components

Classification:	Class IIb
Device Group:	B010102 - HOMOLOGOUS DONOR BLOOD COLLECTION BAGS AND KITS
Intended Purpose:	Compoflex empty blood donation systems are intended for the collection, processing and/or storage of whole blood or blood components.

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

Revision History:

Rev.	Dated	Report	Description
00	2021-10-18	713198383	-
01	2022-03-10	713215445	-
02	2022-10-25	713235232	-
03	2022-11-18	713235235	-
04	2023-06-21	713207465 / 713211642	Supplemented: Device(s)/group of device(s) added
05	2024-09-26	713235231 / 713310265	Supplemented: Device(s)/group of device(s) added
06	2026-06-22	713315316	Supplemented: Device(s)/group of device(s) added

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