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

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

Certificate No. G15 037258 0061 Rev. 00

Manufacturer:

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

SRN Manufacturer - DE-MF-000009273

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 (excluding custom-made implantable devices) 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 037258 0061 Rev. 00

Report No.:	713417933; 713417932; 713403387
Preceding Certificate No.:	G10 037258 0014 Rev. 06 G11 037258 0015 Rev. 01 G11 037258 0029 Rev. 00 G12 037258 0016 Rev. 01
Valid from:	2026-10-18
Valid until:	2031-10-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-08-28

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Classification:	Class IIa
Device Group:	MDA 0306 - Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis
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
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:	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:	B020102 - LABORATORY LEUKOREDUCTION FILTERS
Intended Purpose:	Filters are medical devices intended for leukocyte reduction of blood components for transfusion
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:	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
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:	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

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	Red Cells, Plasma and Platelet Rich Plasma
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 I
Device Group:	B04 - AUTOTRANSFUSION DEVICES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A02 - SYRINGES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A03 - TUBULAR DEVICES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A06 - DRAINAGE AND FLUIDS COLLECTION DEVICES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A07 - ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	A08 - NUTRITION AND INFUSION BAGS AND CONTAINERS, SINGLE-USE
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	G02 - GASTROINTESTINAL TUBES AND SETS
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class I
Device Group:	V02 - NEONATOLOGY AND PAEDIATRIC DEVICES
Device Properties:	MDS 1005 - Devices in sterile condition
Classification:	Class IIb
Device Group:	G020299 - GASTROINTESTINAL FEEDING/ASPIRATION TUBES - OTHER
Intended Purpose:	Percutaneous intragastric long-term feeding and gastric decompression / drainage by gravity For long-term intestinal feeding after abdominal or laparoscopic procedures

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

Revision History:

Rev.	Dated	Report	Description
00	2026-10-18	713417933; 713417932; 713403387	Renewal of certificate Administrative merge / transfer to new Certificate Type

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