



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 077174 0005 Rev. 09

Manufacturer:

Fresenius Medical Care AG

Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY

SRN Manufacturer - DE-MF-000008193

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 077174 0005 Rev. 09

Report No.: 713336688

Preceding Certificate No.: G10 077174 0005 Rev. 08

Valid from: 2025-09-24

Valid until: 2030-06-18

Date of Initial Issuance: 2020-06-19

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-09-24



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Classification:	Class IIa
Device Group:	B030201 - PLASMAPHERESIS DEVICES AND KITS B030203 - SINGLE PLASMA COMPONENTS REMOVAL DEVICES AND KITS B030299 - APHERESIS THERAPY DEVICES - OTHER B0380 - APHERESIS DEVICES - ACCESSORIES F020101 - ARTERIOVENOUS DIALYSIS LINES, ONE NEEDLE F020102 - ARTERIOVENOUS DIALYSIS LINES, TWO NEEDLES F020201 - PERMANENT PERITONAEAL DIALYSIS LINES F02020201 - TEMPORARY PERITONAEAL DIALYSIS LINES, GRAVITY (APD) F02020202 - TEMPORARY PERITONAEAL DIALYSIS LINES, WITH PUMP (APD) F020280 - PERITONAEAL DIALYSIS LINES - ACCESSORIES F0299 - DIALYSIS LINES - OTHER F900199 - PERITONAEAL DIALYSIS - OTHER F900301 - HAEMODIALYSIS ADAPTORS F900302 - PERITONAEAL DIALYSIS ADAPTORS F9099 - DIALYSIS DEVICES - OTHER Z12099001 - BODY IMPEDANCE ANALYSERS Z12099007 - DIALYSIS WATER TREATMENT SYSTEMS Z12099092 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS INSTRUMENTS - MEDICAL DEVICE SOFTWARE
Intended Purpose:	-/-
Classification:	Class IIb
Device Group:	B030203 - SINGLE PLASMA COMPONENTS REMOVAL DEVICES AND KITS
Intended Purpose:	Removal of specific substances from blood in an extracorporeal treatment
Classification:	Class IIb
Device Group:	D030101 - HYPOCHLORITE FOR THE DISINFECTION OF MEDICAL DEVICES
Intended Purpose:	Cleaning and chemical disinfection of hydraulic parts of hemodialysis (HD) machines
Classification:	Class IIb
Device Group:	D050101 - PERACETIC AND ACETIC ACID WITH HYDROGEN PEROXIDE FOR THE DISINFECTION OF MEDICAL DEVICES
Intended Purpose:	Chemical disinfection and decalcification of hydraulic parts of hemodialysis (HD) machines and water treatment systems



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Classification:	Class IIb
Device Group:	D0899 - DETERGENTS FOR MEDICAL DEVICES - OTHER
Intended Purpose:	Cleaning, decalcification and chemo-thermal disinfection of hydraulic parts of hemodialysis (HD) machines
Classification:	Class IIb
Device Group:	F01060103 - DIALYSERS - UFC < 18 ml/h/mmHg, SYNTHETIC MEMBRANES F01060203 - DIALYSERS - UFC = 18 - 35 ml/h/mmHg, SYNTHETIC MEMBRANES F01060303 - DIALYSERS - UFC > 35 ml/h/mmHg, SYNTHETIC MEMBRANES
Intended Purpose:	Removal of uremic toxins including excess water and correction of blood electrolytes and acid-base balance in an extracorporeal treatment
Classification:	Class IIb
Device Group:	F040101 - DIALYSIS CONCENTRATES, ACID SOLUTIONS, NON-STERILE
Intended Purpose:	Correction of blood electrolytes and acid-base balance
Classification:	Class IIb
Device Group:	F040201 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, POWDER
Intended Purpose:	Correction of blood electrolytes and acid-base balance
Classification:	Class IIb
Device Group:	F040399 - DIALYSIS CONCENTRATES, WITHOUT ACETATE BUFFER FOR OTHER TREATMENTS
Intended Purpose:	Correction of blood electrolytes and acid-base balance in an extracorporeal dialysis treatment
Classification:	Class IIb
Device Group:	Z120901 - PERITONEAL DIALYSIS INSTRUMENTS
Intended Purpose:	Control, operation and monitoring of peritoneal dialysis treatment
Classification:	Class IIb
Device Group:	Z120902 - HAEMODIALYSIS INSTRUMENTS
Intended Purpose:	Control, operation and monitoring of extracorporeal dialysis treatment



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Classification: Class IIb
Device Group: Z120902 - HAEMODIALYSIS INSTRUMENTS
Intended Purpose: Control, operation and monitoring of extracorporeal treatment

Classification: Class IIb
Device Group: Z12099006 - LIQUID DIALYSIS PREPARATIONS
Intended Purpose: Preparation and central supply of dialysis concentrate

Classification: Class IIb
Device Group: Z12099007 - DIALYSIS WATER TREATMENT SYSTEMS
Intended Purpose: Provision of dialysis water for dialysis treatment

The validity of this certificate depends on conditions and/or is limited to the following: -/-

Revision History:

Rev.	Dated	Report	Description
00	2020-06-19	713167812	-
01	2021-07-05	713202281	-
02	2022-04-08	713203798	-
03	2022-10-18	713219192	-
04	2023-12-01	713315153	Supplemented: Other
05	2024-05-14	713271450	Supplemented: Device(s)/group of device(s) added
06	2025-02-13	713275525	Supplemented: Device(s)/group of device(s) added
07	2025-06-19	713344383	Renewal of certificate
08	2025-07-28	713336689	Supplemented: Device(s)/group of device(s) added
09	2025-09-24	713336688	Supplemented: Device(s)/group of device(s) added