



## 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. 03**

**Manufacturer:**

**Fresenius Medical Care AG & Co. KGaA**

Else-Kröner-Straße 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 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 077174 0005 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:G10 077174 0005 Rev. 03)

**Report No.:**

713219192

**Preceding Certificate No.:**

G10 077174 0005 Rev. 02

**Valid from:**

2022-10-18

**Valid until:**

2025-06-18

**Date of Initial Issuance:**

2020-06-19

Christoph Dicks

Head of Certification/Notified Body

**Issue date:** 2022-10-18



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**Classification:**

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  
Z12099007 - DIALYSIS WATER TREATMENT SYSTEMS  
Z12099092 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS  
INSTRUMENTS - MEDICAL DEVICE SOFTWARE

**Intended Purpose:**

-/-

**Classification:**

IIb

**Device Group:**

B030299 - APHERESIS THERAPY DEVICES - OTHER

**Intended Purpose:**

Removal of specific substances from blood in an extracorporeal treatment

**Classification:**

IIb

**Device Group:**

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:**

IIb

**Device Group:**

F040101 - DIALYSIS CONCENTRATES, ACID SOLUTIONS,  
NON-STERILE

**Intended Purpose:**

Correction of blood electrolytes and acid-base balance



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<b>Classification:</b>	IIb
<b>Device Group:</b>	F040201 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, POWDER
<b>Intended Purpose:</b>	Correction of blood electrolytes and acid-base balance
<b>Classification:</b>	IIb
<b>Device Group:</b>	F040399 - DIALYSIS CONCENTRATES, WITHOUT ACETATE BUFFER FOR OTHER TREATMENTS
<b>Intended Purpose:</b>	Correction of blood electrolytes and acid-base balance in an extracorporeal dialysis treatment
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z120901 - PERITONEAL DIALYSIS INSTRUMENTS
<b>Intended Purpose:</b>	Control, operation and monitoring of peritoneal dialysis treatment
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z120902 - HAEMODIALYSIS INSTRUMENTS
<b>Intended Purpose:</b>	Control, operation and monitoring of extracorporeal dialysis treatment
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z120902 - HAEMODIALYSIS INSTRUMENTS
<b>Intended Purpose:</b>	Control, operation and monitoring of extracorporeal treatment
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z12099006 - LIQUID DIALYSIS PREPARATIONS
<b>Intended Purpose:</b>	Preparation and central supply of dialysis concentrate
<b>Classification:</b>	IIb
<b>Device Group:</b>	Z12099007 - DIALYSIS WATER TREATMENT SYSTEMS
<b>Intended Purpose:</b>	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
	00	2020-06-19	713167812
	01	2021-07-05	713202281
	02	2022-04-08	713203798