

EU DECLARATION OF CONFORMITY

Fresenius Medical Care AG

Else-Kröner-Str. 1 61352 Bad Homburg – Germany SRN: DE-MF-000008193

declares under his sole responsibility that the product

Product Name:	multiFiltratePRO paed HD
Product Code:	F00008936
GMN / Basic UDI-DI:	4039361-0000-0000-0117-NQ
Product Group:	Acute dialysis tubing sets multifiltrate
EMDN Code:	F020102
Intended Purpose:	Channeling of blood and fluid in an extracorporeal treatment

meets the applicable provisions as stated below and the relevant standards and common specifications as specified in the technical documentation.

Applicable regulation/s:	European Medical Device Regulation 2017/745
Risk class: (according to Annex VIII Medical Device Regulation 2017/745)	Class IIa according to Rule 2
Conformity assessment procedure:	Annex IX (Chapters I and III) of the Regulation (EU) 2017/745 (MDR)
Notified body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München – Germany
Notified body no.:	0123
EU certificate:	G10 077174 0005
Place, Date:	Bad Homburg, 01-Dec-2023

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Dr. Rüdiger Amberg Product Center Responsible Person

Dr. Thomas Himstedt Responsible person acc. MDR Art. 15

This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.

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Property of Fresenius Medical Care