

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 Ci-Ca HDF*
Product Code: *F00001654*
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: *Class IIa according to Rule 2*
(according to Annex VIII Medical Device Regulation 2017/745)
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*

i.V.


Dr. Rüdiger Amberg
Product Center Responsible Person

ppa


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This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.