

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: *6008 CAREset-R*
Product Code: *F00006808*
GMN / Basic UDI-DI: *4039361-0000-0000-0115-NJ*
Product Group: *Haemodialysis tubing sets 6008*
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