

# 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 Low Volume-R*  
Product Code: *F00007578*  
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