

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: *Filtrate Bag 10 L*
Product Code: *F00007116*
GMN / Basic UDI-DI: *4039361-0000-0000-0120-N8*
Product Group: *Acute dialysis drainage sets*
EMDN Code: *F0299*
Intended Purpose: *Collection of waste 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 I according to Rule 1*
(according to Annex VIII Medical Device Regulation 2017/745)
Conformity assessment procedure: *Art. 52(7) & Annex IV (Declaration of Conformity) according Regulation (EU) 2017/745 (MDR)*
Notified body: *Not applicable*
Notified body no.: *Not applicable*
EU certificate: *Not applicable*
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