

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: *DALI 750 Adsorber*
Product Code: *9795311*
GMN / Basic UDI-DI: *4039361-0000-0000-0034-NJ*
Product Group: *DALI adsorbers*
EMDN: *B030299*
Intended Purpose: *Removal of specific substances from blood 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 IIb according to Rule 3*
(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*

Christian Peis
i.V. _____
Christian Peis
Product Center Responsible Person

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This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.