FRESENIUS MEDICAL CARE

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:	*Ci-Ca Dialysate K2 Plus 5000 mL*
Product Code:	*F00009641*
GMN / Basic UDI-DI:	*4039361-0000-0000-0032-NC*
Product Group:	*Dialysis solutions for acute treatment*
EMDN Code:	*F040399*
Intended Purpose:	*Correction of blood electrolytes and acid-base balance in an extracorporeal dialysis 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: (according to Annex VIII Medical Device Regulation 2017/745)	*Class IIb according to Rule 3*
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. _____
Andrea Schorr
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This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.