

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: *F00009649*
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: *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*

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This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.