

EU DECLARATION OF CONFORMITY

P O L A N D

Fresenius Medical Care AG & Co. KGaA

Else-Kröner-Str. 1
61352 Bad Homburg – Germany
SRN: DE-MF-000008193

FOR REGISTRATION PURPOSES ONLY!

declares under his sole responsibility that the product

Product Name: *see attachment*
GMN / Basic UDI-DI: *4039361-0000-0000-0032-NC*
Product group: *Dialysis solutions for acute treatment*
EMDN: *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*

Bad Homburg, 31-Aug-2022

Place and date

DocuSigned by Tiago Barata Ramos

I approve this document
31-Aug-2022 | 2:44:22 PM CEST
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i. V. Tiago Ramos
Manager Medical Device Regulatory Affairs

i. V. Dorothea Hoffmann
Associate Medical Device Regulatory Affairs

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Versions:

Product code	Product name
F00009643	Ci-Ca Dialysate K2 5000 mL
F00009644	Ci-Ca Dialysate K4 5000 mL
F00009645	Ci-Ca Dialysate K2 Plus 5000 mL
F00009646	Ci-Ca Dialysate K4 Plus 5000 mL

Bad Homburg, 31-Aug-2022

Place and date

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