

# 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  
  
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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

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