

## **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: F00009645

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 Annex IX (Chapters I and III) of the Regulation (EU)

procedure: 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

Andrea Schore Dr. Thomas Himstedt

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This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.

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