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:	*Therapy Monitor*
Product Code:	*F988471*
GMN / Basic UDI-DI:	*4039361-0000-0000-0009-NJ*
Product Group:	*Therapy Monitor*
EMDN Code:	*Z12099092*
Intended Purpose:	*Acquire, calculate, save, display and transfer parameters of dialysis treatments*
Software-Version:	*2.3*

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 IIa according to Rule 11*
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*

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i.V. _____
Daniel Pelzl
Product Center Responsible Person

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This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.