

# EU DECLARATION OF CONFORMITY

## Fresenius Medical Care AG & Co. KGaA

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

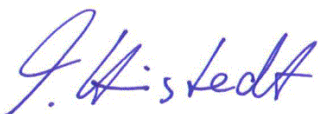
**declares under his sole responsibility that the product**

Product Name: *Therapy Monitor*  
GMN / Basic UDI-DI: *4039361-0000-0000-0009-NJ*  
Product group: *Therapy Monitor*  
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: *Class IIa according to Rule 11*  
(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,*

  
i.V. \_\_\_\_\_  
Dongyan Hua  
Product Center Responsible Person

  
ppa \_\_\_\_\_  
Dr. Thomas Himstedt  
Responsible person acc. MDR Art. 15

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## Versions:

Product code	Product name
F988471	Therapy Monitor

## Accessories:

(according to the European Medical Device Regulation 2017/745)

Product code	Product name
-	-

## Additional equipment:

(Additional equipment which can be used with the respective product, is not covered by this Declaration of Conformity)

Product code	Product name
F988511	Therapy Monitor Advanced Communication
F988521	Therapy Monitor Advanced Medical
F988531	Therapy Monitor Multi Center
M357651	PatientCard
M451291	PatientCard Plus
M348601	BCM PatientCard