

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: *PatientOnLine*
GMN / Basic UDI-DI: *4039361-0000-0000-0010-MU*
Product group: *PatientOnLine (POL)*
Intended Purpose: *Acquire, calculate, save, display and transfer parameters of dialysis treatments*
Software-Version: *6.3*

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
F989901	PatientOnLine
F989951	PatientOnLine Multi-User

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
F989911	PatientOnLine External Interface
F989961	PatientOnLine Multi Center
F00009674	PatientOnLine Connected Home
M357651	PatientCard
M451291	PatientCard Plus
M348601	BCM PatientCard
M396301	SleepSafe PatientCard