

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: *multi*
GMN / Basic UDI-DI: *4039361-0000-0000-0006-N9*
Product group: *multi*
EMDN Code: *Z120902*
Intended Purpose: *Control, operation and monitoring of extracorporeal treatment*
Software Version: *V6.0*

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
- European Directive 2011/65/EU Restriction of Hazardous Substances*

Risk class: *Class IIb according to Rule 12*
(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*

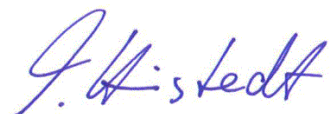
EU certificate: *G10 077174 0005*

Place, Date: *Bad Homburg,*

i.V.


Daniel Pelzl
Product Center Responsible Person

ppa


Dr. Thomas Himstedt
Responsible person acc. MDR Art. 15

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Versions:

Product code	Product name
M205001	multiFiltratePRO
-	-

Accessories:

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

Product code	Product name
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