

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: *stay•safe® Organizer*
GMN / Basic UDI-DI: *4039361-0000-0000-0029-NU*
Product group: *PD handling devices*
Intended Purpose: *Facilitating of handling of other medical devices in a peritoneal 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 I according to Rule 1*
(according to Annex VIII Medical Device Regulation 2017/745)
Conformity assessment procedure: *- Art. 52(7) & Annex IV (Declaration of Conformity) according Regulation (EU) 2017/745 (MDR)*
Notified body: *Not applicable*
Notified body no.: *Not applicable*
EU certificate: *Not applicable*
Place, Date: *Bad Homburg,*

i.V.



Dr. Rüdiger Amberg
Product Center Responsible Person

ppa



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

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Versions:

Product code	Product name
2842561N	stay•safe® Organizer

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
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