

# 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: *stay safe Organizer*  
Product Code: *2842561N*  
GMN / Basic UDI-DI: *4039361-0000-0000-0029-NU*  
Product Group: *PD handling devices*  
EMDN Code: *F900199*  
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, 01-Dec-2023*

i.V. *Andrea Schorr*  
Andrea Schorr  
Product Center Responsible Person

*Thomas Himsfeldt*  
ppa  
Dr. Thomas Himsfeldt  
Responsible person acc. MDR Art. 15