

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:	Clip for stay safe Organizer
Product Code:	F00006845
GMN / Basic UDI-DI:	4039361-0000-0000-0029-NU
Product Group:	PD handling devices
EMDN:	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: (according to Annex VIII Medical Device Regulation 2017/745)	Class I according to Rule 1
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

andrea Schorr i.V. Andrea Schorr

Product Center Responsible Person

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

This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.

ppa