FRESENIUS MEDICAL CARE

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:	*SILENCIA*
Product Code:	*M207001*
GMN / Basic UDI-DI:	*4039361-0000-0000-0005-N6*
Product Group:	*Silencia PD machines*
EMDN Code:	*Z120901*
Intended Purpose:	*Control, operation and monitoring of peritoneal dialysis treatment*
Software Version	*2.0*

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: (according to Annex VIII Medical Device Regulation 2017/745)	*Class IIb according to Rule 12*
Conformity assessment procedure:	*Annex IX (Chapters I and III) of the Regulation (EU) 2017/745 (MDR)*
Notified body: (according to Medical Device Regulation 2017/745)	*TÜV SÜD Product Service GmbH* *Ridlerstraße 65* *80339 München – Germany*
Notified body no.:	*0123*
EU certificate:	*G10 077174 0005*
Place, Date:	*Bad Homburg, 01-Dec-2023*

i.V. Christian Barth
Christian Barth
Product Center Responsible Person

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This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.