

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: *Dialysis Concentrate Distribution Loop (DCDL)*
GMN / Basic UDI-DI: *4039361-0000-0000-0111-N6*
Product group: *Dialysis Concentrate Distribution Loop*
EMDN Code: *F9099*
Intended Purpose: *Central supply of dialysis concentrate*

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 IIa according to Rule 2*
(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*
(according to Annex VIII Medical Device Regulation 2017/745) *Ridlerstraße 65
80339 München – Germany*

Notified body no.: *0123*

EU certificate: *G10 077174 0005*

Place, Date: *Bad Homburg, 01-Dec-2023*

i.V. 
Bünyamin Yildirim
Product Center Responsible Person

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

EU DECLARATION OF CONFORMITY

Versions:

Product code	Product name
6346501	Dialysis concentrate distribution loop

Accessories:

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

Product code:	Product name:
6309241	Tube PE 8x12mm white Length 100m
M512671	Tube PE red 8x12mm Length 100m
M512681	Tube PE blue 8x12mm Length 100m
5453721	Tube tissue white d6mm
F40005702	Double connector Ø8 PPSU
F40005703	Concentrate connector 0-0°
F40005704	Concentrate connector 45-0°
F40005705	Concentrate connector 0- 45°
F40005755	Concentrate connector K0 MediaR
F00010501	Concentrate block 2x straight MediaC/P
F00010502	Concentrate unit C1 double - MediaC/P
F00010503	Concentrate unit C2 double - MediaC/P
F00010504	Concentrate unit C3 double - MediaC/P
F00010855	Modul Concentrate block MediaR - incl. Nozzle
F40005667	Nipple, Closure concentrate DN4, G1/4", PPSU
6349731	Nipple, Closure concentrate DN4,G1/4",PVDF/O-Ring
F00010505	Concentrate nipple PPSU incl. seal
F00010506	Concentrate nipple PVDF incl. seal
6311011	O-Ring EPDM 4x4
M026391	Hose clamp 1-ear 14,5 RER; Productgroup 154

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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: *Dialysis water distribution loop (DWDL)*
GMN / Basic UDI-DI: *4039361-0000-0000-0110-N3*
Product group: *Dialysis Water Distribution Loop*
EMDN Code: *F9099*
Intended Purpose: *Central supply of dialysis water*

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 IIa according to Rule 2*
(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*
(according to Annex VIII Medical Device Regulation 2017/745)

Notified body no.: *0123*

EU certificate: *G10 077174 0005*

Place, Date: *Bad Homburg, 01-Dec-2023*

i.V. 
Bünyamin Yıldırım
Product Center Responsible Person

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

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Versions:

Product code	Product name
6346511	Dialysis water distribution loop (DWDL)

Accessories:

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

Product code:	Product name:
6345031	VPE-Pipe PEX 25x3,5MM (100m Ring)
6309351	VPE-Pipe PEX 25x3,5MM (50m Ring)
6316031	Connector 90°F.PEX 25X3,5mm S/S*Inst.FWT
6325801	Connector 180°F.PEX 25X3,5MM S/S Inst.FWT
6316041	Connector Straight for PEX 25X3,5MM S/S
F00010873	PEX-connector complete
F40000559	Permeate connector MediaP/MediaC
F00007306	Single Dialysis Water connection 90°
F00010494	Permeateblock MediaC/P single 90°
F00007307	Double Dialysis Water connection 90°
F00010495	Permeateblock MediaC/P double 90°
G03000526	Permeate connector P1A2 - PEX-A PEX-Connection/ Drain
F00010826	Modul Permeate MediaR
F00010492	Permeateblock MediaC/P single straight
F00010493	Permeateblock MediaC/P double straight
6311081	Closure Nipple NW 6-R 1/4"-11mm Permeate
E04000117	Closure nipple NW 6-G 1/4"-11mm Permeate
F00010499	Permeatenipple Walther incl. seal
F00010500	Permeatenipple Fidica incl. seal
6366021	Flat seal EPDM 11,5 x 5 x 3,6
F00006459	Fluid Fly Loop secondary ring main 4m, strain relief ring nut, Device connection nipple without sampling port
F00006458	Fluid Fly Loop secondary ring main 4m, strain relief ring nut, Device connection nipple with sampling port
6309401	Sliding sleeve 25x3,5mm PVDF

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