

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: *AquaA 900H*
Product Code: *F00001429*
GMN / Basic UDI-DI: *4039361-0000-0000-0102-N4*
Product Group: *AquaA*
EMDN Code: *Z12099007*
Intended Purpose: *Provision of dialysis water for 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
- European Directive 2011/65/EU Restriction of Hazardous Substances*

Risk class: *Class IIb according to Rule 12*
(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)*

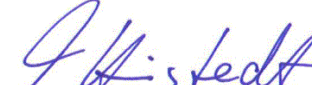
Notified body: *TÜV SÜD Product Service GmbH*
(according to Medical Device Regulation 2017/745) *Ridlerstraße 65
80339 München – Germany*

Notified body no.: *0123*

EU certificate: *G10 077174 0005*

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

i.V. 
Bünyamin Yıldırım
Product Center Responsible Person

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

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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: *AquaA 1000*
Product Code: *6347511*
GMN / Basic UDI-DI: *4039361-0000-0000-0102-N4*
Product Group: *AquaA*
EMDN Code: *Z12099007*
Intended Purpose: *Provision of dialysis water for dialysis treatment*

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Product Name: *AquaA 1800H*
Product Code: *F00001430*
GMN / Basic UDI-DI: *4039361-0000-0000-0102-N4*
Product Group: *AquaA*
EMDN Code: *Z12099007*
Intended Purpose: *Provision of dialysis water for dialysis treatment*

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Product Name: *AquaA 2000*
Product Code: *6347521*
GMN / Basic UDI-DI: *4039361-0000-0000-0102-N4*
Product Group: *AquaA*
EMDN Code: *Z12099007*
Intended Purpose: *Provision of dialysis water for dialysis treatment*

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Product Name: *AquaA 2700H*
Product Code: *F00001431*
GMN / Basic UDI-DI: *4039361-0000-0000-0102-N4*
Product Group: *AquaA*
EMDN Code: *Z12099007*
Intended Purpose: *Provision of dialysis water for 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
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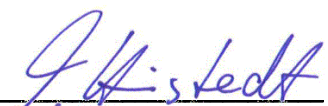
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61352 Bad Homburg – Germany
SRN: DE-MF-000008193

declares under his sole responsibility that the product

Product Name: *AquaA 3000*
Product Code: *6347531*
GMN / Basic UDI-DI: *4039361-0000-0000-0102-N4*
Product Group: *AquaA*
EMDN Code: *Z12099007*
Intended Purpose: *Provision of dialysis water for dialysis treatment*

meets the applicable provisions as stated below and the relevant standards and common specifications as specified in the technical documentation.

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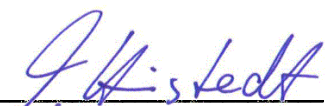
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SRN: DE-MF-000008193

declares under his sole responsibility that the product

Product Name: *AquaA 3600H*
Product Code: *F00001432*
GMN / Basic UDI-DI: *4039361-0000-0000-0102-N4*
Product Group: *AquaA*
EMDN Code: *Z12099007*
Intended Purpose: *Provision of dialysis water for dialysis treatment*

meets the applicable provisions as stated below and the relevant standards and common specifications as specified in the technical documentation.

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61352 Bad Homburg – Germany
SRN: DE-MF-000008193

declares under his sole responsibility that the product

Product Name: *AquaA 4000*
Product Code: *6347541*
GMN / Basic UDI-DI: *4039361-0000-0000-0102-N4*
Product Group: *AquaA*
EMDN Code: *Z12099007*
Intended Purpose: *Provision of dialysis water for dialysis treatment*

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