EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

DWA GmbH & Co.KG
Großer Sand 8
76698 Ubstadt-Weiher
Germany

Digitally signed by Moraru Grigore
Date: 2024.06.07 11:12:11 EEST
Reason: MoldSign Signature
Location: Moldova

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III and Class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

Single Registration Number of the Manufacturer (SRN):	DE-MF-000008370
Authorised Representative:	N/A
The validity of this EU Certificate depends on conditions and / or is limited to the following:	--
List of Products, Risk Classification and Details:	see Section 2
Certificate history:	see Section 3

Reg.-No.: 44 911 150580
Certification decision report No.: 3535 1781

Edition:	2
Issue date:	2023-06-30
First issued:	2023-05-05
Valid until:	2028-05-04

Essen, 2023-07-25

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

TÜV NORD CERT GmbH
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medical@tuev-nord.de
TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

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Reg. No. 44 911 150580 Section 2, List of Products

Class IIb (non implantable)

Product name	Intended purpose	Generic device group (EMDN)	Technical documentation assessment report number
HemoRO 4 ONE centRO modula S, modula S-XL, modula S-TP modula TP, modula	The device produces dialysis water by means of reverse osmosis and provides it to one or more dialysis equipments that are connected directly or through Media Supply Systems.	Z12099007	3533 1514

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Reg. No. 44 911 150580 Section 3, Certificate History

Certificate History

Edition	Date	Action leading to revision	Certification decision report number
01	2023-05-05	Initial issuance	ZA 3533 1514
02	2023-07-18	Change notification 1	ZA 3535 1781

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