

# Certificate

acc. to **ISO 13485:2016**

Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

Certificate Registration No.: **21-1607-M**

TUV USA, Inc. hereby certifies that the quality management system of the company mentioned below is in conformance with ISO 13485:2016 under MDSAP for Medical Devices Requirements under the following jurisdictions:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure. **Canada:** Medical Devices Regulations – Part 1- SOR/98-282.

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

Facility ID: **F003843**

Additional sites covered by QM System: **N/A**

List of Products: **See Annex 1**

Scope:

**Design, development, manufacture and distribution of units and systems for production and preparation of pure water and concentrates for dialysis**

The validity of this certification document can be obtained by contacting the TUV USA, Inc. Office.

TUV USA, Inc. (a Member of the TÜV NORD Group)

215 Main Street, Suite 1, Salem, NH 03079, USA

Tel: 001-603-870-8023, Fax: 001-603-870-8026, Email: [medical-usa@tuv-nord.com](mailto:medical-usa@tuv-nord.com)

*TUV USA, Inc. is an MDSAP Recognised Auditing Organization*



Audit Report Reference No.: **20-3886 RC-CA**

Certificate Initial Issue Date: **2021-05-11**

Current Cycle Start Date: **2021-05-11**

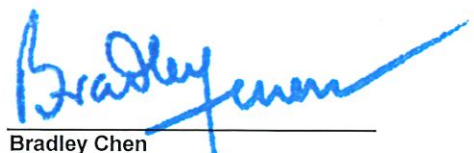
Certificate Revised Date: **N/A**

Effective Date:

**2021-05-11 / ed. 1**

Valid Until:

**2024-05-10**



Bradley Chen  
Vice President – Medical, Americas  
Medical Products Division  
TUV USA, Inc.

**Annex 1, page 1 of 1**  
(Annex 1 MUST be displayed with the main certificate)

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**Company Name:** DWA GmbH & Co. KG  
**Central Office Address:** Großer Sand 8, 76698 Ubstadt-Weiher, Germany



<b>Products</b>	<b>UMDNS</b>	<b>GMDN</b>
Concentrate Supply Unit	11-211	34993
Reverse Osmosis System	14-437	14437
Heat Disinfection Systems	11-211	62203

---End of list---

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