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
TUV USA, Inc. is an MDSAP Recognised Auditing Organization

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

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.

Certificate Registration No. : **21-1607-M / ed. 1**
Company Name: ***DWA GmbH & Co. KG***
Central Office Address: ***Großer Sand 8, 76698 Ubstadt-Weiher, Germany***

Products	**UMDNS**	**GMDN**
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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