

TÜV SÜD
CERTIFICATE ◆ CERTIFICADO ◆ CERTIFIKAT ◆ 認證證書 ◆ CERTIFICATE ◆ CERTIFIKAT



America

CERTIFICATE

No. QS6 031095 0052 Rev. 00

Certificate Holder: Lauer
Membran Wassertechnik GmbH
Speichermatt 9
79599 Wittlingen
GERMANY



Scope of Certificate: Design and Development, Manufacturing and Service of Reverse Osmosis Systems, Central Concentrate Supply, Ring Piping and Hot Rinse Disinfection Systems

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Health Canada, USA FDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 32-824-6251

Effective Date: 2019-03-28

Expiry Date: 2022-03-27

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Date of Issue: 2019-03-29

(Arie Henkin)
Manager, Certification Body MHS

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Regulatory Requirements: Audit/Certification Criteria

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Facility(ies):

Lauer Membran Wassertechnik GmbH
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Facility Scopes:

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