MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 096617 0005 Rev. 00

Certificate Holder: **Manfred Sauer GmbH**
Neurott 7-15
74931 Lobbach
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Manufacturing and Distribution of Continence Systems, Accessories and Handling Aids**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada. 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: **55-150-1575**

Effective Date: **2019-01-15**

Expiry Date: **2022-01-14**

Date of Issue: 2019-01-16

(Arie Henkin)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

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

Facility(ies): Manfred Sauer GmbH
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