



America

CERTIFICATE

No. QS6 096617 0005 Rev. 02**Certificate Holder:**

Manfred Sauer GmbH
Neurott 7-15
74931 Lobbach
GERMANY

Certification Mark:**Scope of Certificate:**

Design and Development, Manufacturing and Distribution of Sterile Single-Use Catheters for Intermittent Self-Catheterization (ISC) or Carer-Assisted Clean Intermittent Catheterization (CIC), Sterile and Non-Sterile Urine Bags for Collection of Urine, Urinary Sheaths for External Urinary Drainage and Accessories for Fixation of Urine Bags and Urinary Sheaths

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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6 096617 0005 Rev. 02

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

REPs Facility ID:**F001268****Report No.:****713311847****Effective Date:****2024-03-13****Expiry Date:****2027-03-12**

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(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada

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

Facility(ies):

Manfred Sauer GmbH

Neurott 7-15, 74931 Lobbach, GERMANY

Facility Scopes:

Design and Development, Manufacturing and Distribution of Sterile Single-Use Catheters for Intermittent Self-Catheterization (ISC) or Carer-Assisted Clean Intermittent Catheterization (CIC), Sterile and Non-Sterile Urine Bags for Collection of Urine, Urinary Sheaths for External Urinary Drainage and Accessories for Fixation of Urine Bags and Urinary Sheaths
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