



Certificate

No. Q5 096617 0004 Rev. 02

Holder of Certificate: **Manfred Sauer GmbH**

Neurott 7-15
74931 Lobbach
GERMANY

Facility(ies):

Manfred Sauer GmbH

Neurott 7-15, 74931 Lobbach, GERMANY

See Scope of Certificate

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

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5_096617_0004_Rev.02

Report No.: 713311847

Valid from: 2024-05-29

Valid until: 2027-05-28

Date, 2024-05-29

Christoph Dicks

Head of Certification/Notified Body