



Certificate

No. Q5 010393 0530 Rev. 06

Holder of Certificate: **CODAN Medizinische Geräte GmbH**
Stig Husted-Andersen Strasse 11
23738 Lensahn
GERMANY

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Sterile and Non-Sterile Single-Use Medical Devices for Infusion and Transfusion Therapy, Irrigation Sets for Urology and Gynaecology as well as Mixing and Withdraw Products. The provision of ETO sterilization service for medical devices.**

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 010393 0530 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:Q5_010393_0530_Rev.06)

Report No.: 713319928

Valid from: 2024-07-23

Valid until: 2026-08-21

Date, 2024-07-23



Christoph Dicks
Head of Certification/Notified Body

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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

Facility(ies): **CODAN Medizinische Geräte GmbH**
Stig Husted-Andersen Strasse 11, 23738 Lensahn, GERMANY

See Scope of Certificate

CODAN Medizinische Geräte GmbH
Bäderstrasse 14, 23738 Lensahn, GERMANY

Packaging laboratory for testing of sterile barrier systems for
Medical Devices according to Scope of Certificate

CODAN Medizinische Polymertechnologie GmbH
Stig Husted-Andersen Strasse 11, 23738 Lensahn, GERMANY

Production of Medical Devices according to Scope of Certificate

CODAN PORTUGAL Instrumentos Médicos, S.A.
Rua Stig Husted-Andersen, 4, 2675-492 Odivelas, PORTUGAL

Production of Medical Devices according to Scope of Certificate

CODAN PORTUGAL Instrumentos Médicos, S.A.
External Warehouse

Estrada da Paiã, Casal da Troca, Nave 3, 1675-089 Pontinha -
Odivelas, PORTUGAL

Provision of warehousing of materials for production of Medical
Devices according to Scope of Certificate