ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
Medical Device Single Audit Program

America

CERTIFICATE

No. QS6 102326 0003 Rev. 00

Certificate Holder: **Thora Tech GmbH**
Gutfleischstr. 3-5
35390 Gießen
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Monitoring and Ventilator Systems and Non-Active Non-Implantable Devices in Sterile Condition for Anesthesia, Emergency and Intensive Care or Sterile Intubation**

Contract Design and Development Services of Ventilator Systems

Contract Development Services Respiratory and Sleep Diagnostic Medical Devices and relevant Medical Device Software

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

Regulatory Authority(ies): **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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 102326 0003 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F008274**
Report No.: **713371621**
Effective Date: **2026-01-08**
Expiry Date: **2029-01-07**

Date of Issue: 2026-01-13

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
Medical Device Single Audit Program

TÜV SÜD America

CERTIFICATE

No. QS6 102326 0003 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies): **Thora Tech GmbH**
Gutfleischstr. 3-5, 35390 Gießen, GERMANY

Facility Scopes:

Design and Development, Production and Distribution of Monitoring and Ventilator Systems and Non-Active Non-Implantable Devices in Sterile Condition for Anesthesia, Emergency and Intensive Care or Sterile Intubation

Contract Design and Development Services of Ventilator Systems

Contract Development Services Respiratory and Sleep Diagnostic Medical Devices and relevant Medical Device Software

REPs Facility ID: F008274

Date of Issue: 2026-01-13

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com