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

MDSAP
Medical Device Single Audit Program

America

CERTIFICATE

No. QS6 121593 0003 Rev. 00

Certificate Holder: **LAUDA Medical GmbH & Co. KG**
Friedrich-Bergius-Ring 22
97076 Würzburg
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution and Service of Heater/Cooler Devices for Patients Tempering**

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

Regulatory Authority(ies): **Health Canada, 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 121593 0003 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F008291**
Report No.: **713373242**
Effective Date: **2025-10-20**
Expiry Date: **2028-10-19**

Date of Issue: 2025-10-27

(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 121593 0003 Rev. 00

Regulatory Requirements: **Audit/Certification Criteria**

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

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

Facility(ies): **LAUDA Medical GmbH & Co. KG**
Friedrich-Bergius-Ring 22, 97076 Würzburg, GERMANY

Facility Scopes: Design and Development, Production, Distribution and Service of Heater/Cooler Devices for Patients Tempering

REPs Facility ID: F008291

Date of Issue: 2025-10-27

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

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