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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 041505 0135 Rev. 05

Certificate Holder: **SCHILLER AG**
Altgasse 68
6341 Baar
SWITZERLAND

Certification Mark:

Scope of Certificate: **Design and Development, Production, Service and Distribution of Electrocardiographs, Sphygmomanometers, Spirometers, Monitoring Devices, Monitoring Systems, Cardiopulmonary Exercise Testing Systems, Defibrillators, Telemetry Devices and Cardiopulmonary Resuscitation Devices**

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

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, 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 041505 0135 Rev. 05
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001334**
Report No.: **713317075**
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Expiry Date: **2027-06-25**

Date of Issue: 2024-05-08

(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

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820
- 21 CFR Part 821

Facility(ies):

SCHILLER AG
Altgasse 68, 6341 Baar, SWITZERLAND

SCHILLER Engineering Austria GmbH
Defreggergasse 5, 8020 Graz, AUSTRIA

Date of Issue: 2024-05-08

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C E R T I F I C A T E

No. QS6 041505 0135 Rev. 05

Facility Scopes:

SCHILLER AG
Altgasse 68, 6341 Baar, SWITZERLAND

Design and Development, Production, Service and Distribution of Electrocardiographs, Sphygmomanometers, Spirometers, Monitoring Devices, Monitoring Systems, Cardiopulmonary Exercise Testing Systems, Defibrillators, Telemetry Devices and Cardiopulmonary Resuscitation Devices
REPs Facility ID: F001334

SCHILLER Engineering Austria GmbH
Defreggergasse 5, 8020 Graz, AUSTRIA

Design of ECG Holter and Analysis Software
REPs Facility ID: F002231

Date of Issue: 2024-05-08

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