

Certificate

Certificate No.: MD 1087205-230

Manufacturer: **GETEMED Medizin- und Informationstechnik AG**

Oderstr. 77
14513 Teltow
Germany

REPs Facility ID: F001090

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

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

Scope: Design and Development, Production, Distribution, Installation and Service of vital signs monitors, cardiac function diagnostic and telemonitoring systems as well as ECG cables

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 1087205-230

Issue Date: 2021-11-22

Effective Date: 2021-12-01

Expiry Date: 2024-11-30



Certification officer: Dipl.-Ing. S. Pane
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/0000027222?locale=en or calling 1-888-743-4652.

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The scope of certification includes the following locations:

No.	Location	Scope
/01	GETEMED Medizin- und Informationstechnik AG Oderstr. 77 14513 Teltow Germany REPs ID: F001090	Design and Development, Production, Distribution, Installation and Servicing of vital signs monitors, cardiac function diagnostic and telemonitoring systems as well as ECG cables
/02	GETEMED Medizin- und Informationstechnik AG Otto-Schmerbach-Str. 19 09117 Chemnitz Germany REPs ID: F002014	Design and Development

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