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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 088852 0004 Rev. 03

Certificate Holder:

MIR–
MEDICAL INTERNATIONAL RESEARCH S.P.A.
Viale Luigi Schiavonetti 270
00173 ROMA RM
ITALY

Certification Mark:

Scope of Certificate:

Design and Development, Manufacture, Service and Distribution of Oximeters and Spirometers including Flowmeters and Mouthpiece for the area of Respiratory Functionality and Cardiac Monitoring Device for the area of Cardiovascular Analysis

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 088852 0004 Rev. 03
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001290**
Report No.: **ITA1477847157**
Effective Date: **2024-01-02**
Expiry Date: **2024-05-31**

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(Renee Walker)
Director, US Certification Body, MHS

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C E R T I F I C A T E

No. QS6 088852 0004 Rev. 03

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

Facility(ies): **MIR– MEDICAL INTERNATIONAL RESEARCH S.P.A.**
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