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America

CERTIFICATE

No. QS6 18 05 88852 003

Certificate Holder: MIR S.r.l.
Medical International Research
Via del Maggiolino 125
00155 ROMA RM
ITALY

Certification Mark:

Scope of Certificate: Design, Development and Manufacturing of Medical Devices for Respiratory Functionality

Standard(s): ISO 13485:2016

Regulatory Authority: Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA.
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. Validity of this certificate can be obtained by visiting the website
http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 63-012-9930
Effective Date: 2018-06-01
Expiry Date: 2021-05-31

Manuel Bradaric
MHS Certification Manager

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America

CERTIFICATE

No. QS6 18 05 88852 003

Audit/Certification Criteria

Australia
- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

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

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

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan
- MHLW Ministerial Ordinance No.169, 2004

Effective Date: 2018-06-01
Expiry Date: 2021-05-31

Manuel Bradaric
Certification Manager MHS