



MDSAP CERTIFICATE

Certificate No. 012.22-1/MDSAP

This is to certify that

Air Liquide Medical Systems S.r.l.

Legal headquarter: via Bisceglie 66, 20152 Milano (MI), Italy

Facility ID: F007300

Refer to Attachment to Certificate of Registration for additional certified sites

Operates a

Quality Management System, which complies with the requirements of ISO 13485:2016 and with the requirements of the following Regulatory Authorities

Australia:

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

Canada:

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

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (as applicable)

for the following scope of certification

Design, manufacturing, sales and technical services of aerosoltherapy equipment and related accessories, surgical aspirators and related accessories. Design, manufacturing and sales of masks for sleep therapy and for noninvasive ventilation and related accessories, nebulization spacer for measured MDI, manual resuscitators.

Reference to IMQ files Nos.:

DM22-0084924-01; DM23-0086737-01; DM23-0087335-01; DM24-0100204-01

Effective Date: 2024-02-19

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IMQ

Matteo Raimondi – IMQ MDSAP Director

IMQ is an authorized MDSAP Auditing Organization

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This MDSAP certificate is subjected to the provisions laid down by IMQ in the "Regulation for Conformity Assessment Activities pursuant to Medical Device Single Audit Program (MDSAP) for which IMQ operates as Auditing Organization". The validity of this certificate can be verified by writing to MDSAP@imq.it.

ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No. 012.22-1/MDSAP

Site address	Site scope
Air Liquide Medical Systems S.r.l. Via Bisceglie 66 20152 Milano (MI), Italy Facility ID: F007300	Legal headquarter
Air Liquide Medical Systems S.r.l. Via dei Prati, 62 25073 Bovezzo (BS), Italy Facility ID: F006602	Design, manufacturing, sales and technical services of aerosoltherapy equipment and related accessories, surgical aspirators and related accessories. Design, manufacturing and sales of masks for sleep therapy and for noninvasive ventilation and related accessories, nebulization spacer for measured MDI, manual resuscitators.