



## MDSAP CERTIFICATE

### Certificate No. 012.22-3/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

**Japan:**

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

**Brazil:**

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

**Canada:**

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

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; DM24-0111337-01; DM25-0113773-01

Effective Date: 2025-07-06

Expiry Date: 2028-07-05

Issued on: 2025-07-04

**IMQ**

**Matteo Raimondi – IMQ MDSAP Director**



IMQ S.p.A. is an MDSAP Recognized Auditing Organization

## ATTACHMENT TO CERTIFICATE OF REGISTRATION

These sites are registered under Certificate No. 012.22-3/MDSAP

Site address	Site scope
Air Liquide Medical Systems S.r.l. Via Bisceglie 66 20152 Milano (MI), Italy <b>Facility ID: F007300</b>	Legal headquarter
Air Liquide Medical Systems S.r.l. Via dei Prati, 62 25073 Bovezzo (BS), Italy <b>Facility ID: F006602</b>	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.