MDSAP CERTIFICATE

Certificate No. 012.22/MDSAP

This is to certify that

Air Liquide Medical Systems S.r.l.

Via dei Prati, 62 - 25073 Bovezzo (BS), Italy

Facility ID: F004356

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

Brazil:
• RDC ANVISA n. 665/2022
• RDC ANVISA n. 551/2021
• RDC ANVISA n. 67/2009

Canada:
• Medical Device Regulations – Part 1 - SOR/98-282

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

Original Certification Date:	2022-11-30
Issue Date:	2023-01-24
Certification Effective Date:	2022-11-30
Expiry Date:	2025-07-05

IMQ

Eng. Fulvio Giorgi – IMQ MDSAP Director

IMQ is an authorized MDSAP Auditing Organization