



MDSAP CERTIFICATE

Certificate No. 001.25-0/MDSAP

This is to certify that

COSMED S.r.l.

Via dei Piani di Monte Savello 37, 00041 Albano Laziale (RM), Italy

Facility ID: F008038

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

United States:

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 - Subparts A to D
- 21 CFR Part 820

Canada:

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

for the following scope of certification

Design, manufacturing, distribution and servicing of spirometers, pulmonary function analyzers, stress exercise monitoring system, plethysmograph, indirect calorimeter and flowmeter for the area of evaluation of the respiratory, cardiac and metabolic function

Reference to IMQ files Nos.:
DM25-0113491-01

Effective Date: 2025-01-27
Expiry Date: 2026-11-26

Issued on: 2025-01-27

IMQ

Matteo Raimondi – IMQ MDSAP Director



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