



America

# CERTIFICATE

No. QS6 087353 0005 Rev. 04

**Certificate Holder:** **Cosmed S.r.l.**  
Via dei Piani di Monte Savello 37  
00041 Albano Laziale (RM)  
ITALY

**Certification Mark:**



**Scope of Certificate:** **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**

**Standard(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6\\_087353\\_0005\\_Rev.\\_04](http://www.tuvsud.com/ps-cert?q=cert:QS6_087353_0005_Rev._04)

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

**REPs Facility ID:** **F001209**  
**Report No.:** **ITA2156333**  
**Effective Date:** **2023-11-27**  
**Expiry Date:** **2026-11-26**

Page 1 of 2

Date of Issue: 2023-12-07

( Renee Walker )  
Director, US Certification Body, MHS

# CERTIFICATE

No. QS6 087353 0005 Rev. 04

## Regulatory Requirements: Audit/Certification Criteria

### 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 - Good Manufacturing Practices  
 - RDC ANVISA n. 551/2021  
 - RDC ANVISA n. 67/2009 - Vigilance

### Canada

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

### Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)  
 - Japan PMD Act (as applicable)

### United States

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

## Facility(ies):

### Cosmed S.r.l.

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

## Facility Scopes:

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  
 REPs Facility ID: F001209

Page 2 of 2

Date of Issue: 2023-12-07



( Renee Walker )  
 Director, US Certification Body, MHS