EC Certificate Full Quality Assurance System: Certificate CN19/41013

The management system of

Shenzhen City Teveik Technology Co., Ltd.

6/F, B Bld, No.21, Pinggang Industrial Road, Shiwei Village, Gongming Street, Guangming New District, Shenzhen City, Guangdong Province, 518106, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Reusable SpO2 (Pulse Oxygen Saturation) Sensor, Disposable SpO2 (Pulse Oxygen Saturation) Sensor

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 30 January 2024 and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 03 June 2019
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CN/SZX 49342

Authorised by

Digitally signed by Ceaicovschi Tudor
Date: 2024.01.25 17:23:11 EET
Reason: MoldSign Signature
Location: Moldova

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

DICHIARAZIONE DI CONFORMITÀ
CONFORMITY DECLARATION

Fabbricante/*Manufacturer*: COSMED S.r.l.

Indirizzo/*Address*: Via dei Piani di Monte Savello 37,
Albano Laziale - 00041 Roma (ITALY)
tel: 06-9315492
fax: 06-9314580

fabbricante dei seguenti dispositivi / *manufacturer of the following equipment:*

Pony FX
Pony FX Flowsafe
Pony FX MIP/MEP
microQuark
Spiropalm
Spiropalm Plus
Spiropalm 6MWT

Fitmate
Fitmate Pro

Fitmate Med
Fitmate GS

Quark b^2
K5

Q-Box
Q-i2m

Quark C12x
Quark T12x

Quark PFT1
Quark PFT2
Quark PFT3
Quark PFT4

Quark PFTergo
Quark PFT2ergo
Quark PFT4ergo

Quark Spiro
Quark PFT

Quark CPET
Quark RMR

Q-NRG
Q-NRG+

dichiara sotto la propria responsabilità che:
declares under his sole responsibility that:

- i dispositivi sopra elencati soddisfano tutti i requisiti essenziali richiesti dall'allegato I della Direttiva 93/42/CEE sui Dispositivi Medici, come modificata dalla direttiva 2007/47/CEE;
  the above listed equipment comply with the essential requirements of the Annex I of the Medical Device Directive 93/42/EEC, as modified by the Directive 2007/47/EEC;
- sono classificati in classe IIa;
  are classified in Class IIa;
- sono coperti da certificazione CE ai sensi della direttiva 93/42/CEE, come modificata dalla direttiva 2007/47/CEE, rilasciata da KIWA CERMET (Via Cadriano, 23 - 40057 - Granarolo dell'Emilia (BO) - Italia), ente notificato 0476 (certificato n. MED 9811).
  are CE marked according to the Medical Device Directive 93/42/EEC, as modified by the Directive 2007/47/EEC, and certified by KIWA CERMET (Via Cadriano, 23 - 40057 - Granarolo dell'Emilia (BO) - Italy), notified body 0476 (certificate nr. MED 9811).

I dispositivi sono inoltre conformi alle seguenti specifiche:
The equipment conform with the following specifications:

Sicurezza/*Safety*: IEC 60601-1:2005+A1:2012

Compatibilità EM/*EMC*: IEC 60601-1-2:2014

Quark C12x e Quark T12x sono conformi alle norme IEC 60601-1:2005, IEC 60601-1-2:2007 e alla Norma Particolare EN 60601-2-25:2011
Quark C12x and Quark T12x comply with IEC 60601-1:2005, IEC 60601-1-2:2007 and with the Particular Standard EN 60601-2-25:2011

Albano Laziale, 17/05/2021

COSMED srl
Marco Brugnoli
Amministratore unico / *Managing Director*

Certificate CN13/31315

The management system of

Shenzhen City Teveik Technology Co., Ltd.

6/F, B Bld, No. 21, Pinggang Industrial Road, Shiwei Village, Gongming Street, Guangming New District, Shenzhen City, Guangdong Province, 518106, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design and Manufacture of Reusable SpO2 (Pulse Oxygen Saturation) Sensors, Disposable SpO2 (Pulse Oxygen Saturation) Sensors; Manufacture of ECG (Electrocardiogram) Cables

This certificate is valid from 31 January 2022 until 31 January 2025 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date Issue 4. Certified since 08 November 2013

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 2016 0421

CERTIFICATE

Reg. Number	387 - A	Valid From	2021-04-15
First issue date	1997-12-10	Last change date	2021-04-15
Valid Until	2024-04-24	IAF Sector	19 , 29
Previous expiry date			

Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

COSMED S.r.l.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Design, manufacturing and marketing with own brand of equipment and accessories for cardio pulmonary function testing and for measurement of metabolism.
Marketing of equipment and accessories for the analysis and evaluation of the cardiorespiratory system, for the measurement of metabolism, body composition and rehabilitation

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

COSMED S.r.l.
Registered Headquarters
- Viale Bruno Buozzi, 77 00197 Roma Italia

Certified Sites
- Via dei Piani di Monte Savello, 37 00041 Albano Laziale (RM) Italia

CERTIFICATE

Reg. Number	387 - M	Valid From	2021-04-15
First issue date	2006-10-13	Last change date	2021-04-15
Valid until	2024-04-24		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

COSMED S.r.l.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design, manufacturing and marketing with own brand of equipment and accessories for cardio pulmonary function testing and for measurement of metabolism. Marketing of equipment and accessories for the analysis and evaluation of the cardiorespiratory system, for the measurement of metabolism, body composition and rehabilitation

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

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Kiwa Cermet Italia S.p.A.
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SGQ N° 007A