



Reg. Numero /
Reg. Number MED 9811

Primo rilascio /
First issue date 1998-06-11

Scadenza /
Valid until 2023-04-24

Revisione /
Revision 17

Valido da /
Valid from 2018-04-23

Ultima modifica /
Last change date 2021-05-17

Pagina / Page 1 di / of 5

Certificato CE del Sistema di Garanzia della Qualità *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

COSMED S.r.l.

Sede Operativa / Operational Headquarter:

Via dei Piani di Monte Savello, 37
00041 Albano Laziale, RM - Italia

Sede Legale / Registered Headquarter

Viale Bruno Buozzi, 77
00197 Roma, RM - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Accessori monouso / Disposable accessories

Dispositivi e accessori per la valutazione della funzione respiratoria, cardiaca e metabolica /
Devices and accessories for evaluation of the respiratory, cardiac and metabolic function
Elettrocardiografi / *Electrocardiographs*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 17/05/2021 11:42:22



Organismo Notificato n. 0476
Notified Body nr. 0476



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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Accessori monouso / Disposable accessories

Classe di rischio / Risk class:
II a

Codice NANDO / NANDO codes:
MD 1301

Marca / Brandname:
COSMED

Modello / Model:
Flow Ree

Tipologia / Medical Devices:
Dispositivi e accessori per la valutazione della funzione respiratoria, cardiaca e metabolica / Devices and accessories for evaluation of the respiratory, cardiac and metabolic function

Classe di rischio / Risk class:
II a

Codice NANDO / NANDO codes:
MD 1301, MDS 7010

Marca / Brandname:
COSMED

Modello / Model:
Fitmate Pro

Modello / Model:
Fitmate

Modello / Model:
Fitmate GS

Modello / Model:
Quark RMR

Modello / Model:
microQuark

Modello / Model:
Pony FX

Chief Operating Officer
Giampiero Belcredi

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Dispositivi e accessori per la valutazione della funzione respiratoria, cardiaca e metabolica / Devices and accessories for evaluation of the respiratory, cardiac and metabolic function

Marca / Brandname:

COSMED

Modello / Model:

Pony FX Flowsafe

Modello / Model:

Pony FX MIP/MEP

Modello / Model:

Q-Box

Modello / Model:

Q-i2m

Modello / Model:

Quark i2m

Modello / Model:

Quark NObreath

Modello / Model:

Quark PFT1

Modello / Model:

Quark PFT2

Modello / Model:

Quark PFT3

Modello / Model:

Quark PFT4

Modello / Model:

Quark Spiro

Modello / Model:

Spiropalm

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Marca / Brandname:

COSMED

Modello / Model:

Spiropalm 6MWT

Modello / Model:

Spiropalm Plus

Modello / Model:

Fitmate Med

Modello / Model:

K5

Modello / Model:

Q-NRG; Q-NRG+

Modello / Model:

Quark CPET

Modello / Model:

Quark PFT

Modello / Model:

Quark PFT ergo

Modello / Model:

Quark PFT2ergo

Modello / Model:

Quark PFT4ergo

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Elettrocardiografi / Electrocardiographs

Classe di rischio / Risk class:
II a

Codice NANDO / NANDO codes:
MD 1301

Marca / Brandname:
COSMED

Modello / Model:
Quark C12x

Modello / Model:
Quark T12x

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

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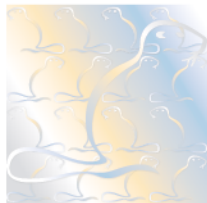
Chief Operating Officer
Giampiero Belcredi

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Data: 17/05/2021 11:43:47

CERMET



Organismo Notificato n. 0476
Notified Body nr. 0476



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.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
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CERMET

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



Pony FX

Desktop Spirometer

“Effective, simple
lung screening in
any environment”



Advanced desktop spirometer with spirometry,
airway resistance and respiratory mechanics



COSMED
The Metabolic Company

“The COSMED Pony FX meets ATS recommendations for accuracy and precision in measuring FVC, FEV₁, FEF_{25-75%} and peak expiratory flow under ambient and BTPS conditions⁽¹⁾”

- I Full spirometry testing (FVC, SVC, MVV, Pre/Post BD)
- I Respiratory Mechanics assessment (MIP/MEP)
- I Airway resistance by Occlusion Technique (option)
- I Oxygen saturimetry with integrated SpO₂ monitor (option)
- I Colour LCD display with real time graphs and embedded high speed thermal printer
- I Validated turbine flowmeter
- I Provided with OMNIA software for data management, real time testing and interpretation on PC



Pressure Transducer with AB filter for MIP/MEP testing



Turbine flowmeter with AB filter for Spirometry testing



Pony FX is the new generation family of portable spirometers from COSMED, representing the ideal solution for flexible lung function screening in many fields of application.

Pony FX design allows easy spirometry testing without sacrificing anything to functionality. Two different Pony FX models are currently available:

Pony FX: desktop spirometer with COSMED validated digital bidirectional turbine flowmeter.

Pony FX MIP/MEP: desktop spirometer with digital turbine and included module for respiratory mechanics measurements (MIP/MEP)

Design

- High quality color LCD display for real time testing
- Integrated 120 mm high speed thermal printer for high quality reports in few seconds
- Compact size and light weight
- Alphanumeric keyboard and navigator tool to allow user access to all functions

- New Li-Ion battery with autonomy of up to 6 hours
- Easy interface with PC and other devices through the ports: USB-A, USB-B, RS 232

Spirometry

- Full spirometry (FVC, SVC, MVV, Pre/post BD)
- New Trial Selection and Quality Control functions (in compliance with ATS/ERS guidelines)
- Innovative pediatric incentivitation with selectable effort grade
- Full compliance with “2005 ATS/ERS consensus” (Interpretation, QC, etc.)
- GOLD COPD interpretation on FVC PostBD
- Includes latest Global Lung Initiative (GLI) predicted (including Z-score)
- ATS, Metacholine-dose, Mannitol and user defined bronchial challenge protocols
- Possibility to download Six Minute Walk Test data from any Spiropalm 6MWT

Respiratory Mechanics (MIP/MEP)

- Measurement of respiratory muscle strength

- Easy to perform, quick, non-invasive
- Either for healthy subjects or patients with pulmonary/neuromuscular diseases
- Special mouth pressuremeter
- Complies with ATS/ERS Guidelines

Data Management & Software

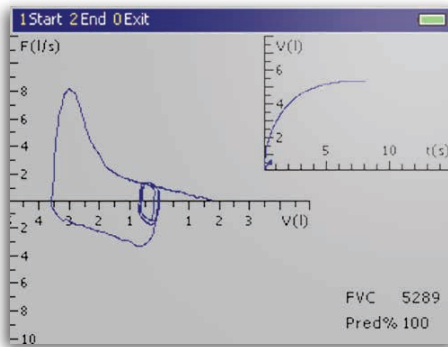
Spirometry tests can be also performed real-time with Pony FX connected to a PC through the powerful software OMNIA.

- Innovative user interface, touch screen, easy and self-explanatory
- Graphical data presentation both at screen and on printouts with gauges (pictograms)
- Powerful algorithm automatically elaborates results and provides comprehensive interpretation text strings including numerical results
- Full customizable time-based trends of main measured parameters
- Access and security compliant to international regulations
- Multi-device management (single license for multiple products)
- Advanced network capabilities (Optional). Running on SQL database.

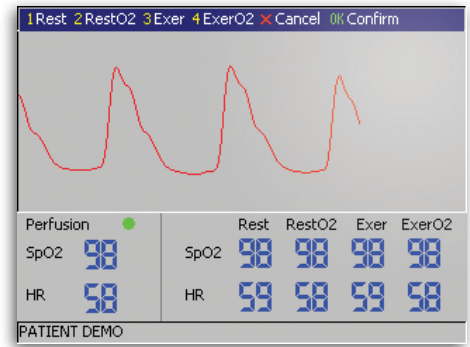
(1) Crapo R. O. (LDS Hospital) 2004 “Validation of COSMED turbine vs ATS 24 standard volume-time waveforms”

Options & Accessories

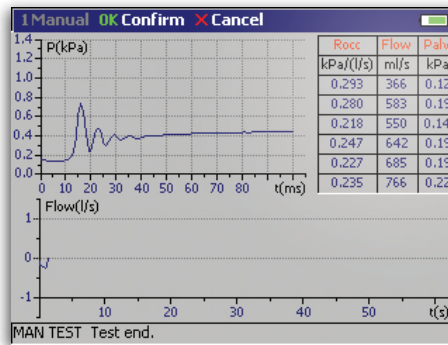
- **Respiratory resistance by interrupter technique (Rint, Rocc).** Ideal solution for testing children (requires low patient collaboration) and good alternative to body plethysmography for airway resistance. Test is performed during tidal breathing through a dedicated low flow PNT mouthpiece while an occlusion valve interrupts the airflow for 100 msec
- **Pulse oximetry (SpO₂).** Oxygen desaturation and heart rate measurement with high quality integrated monitor (Nonin® technology). Low power draw and intelligent pulse-by-pulse filtering.



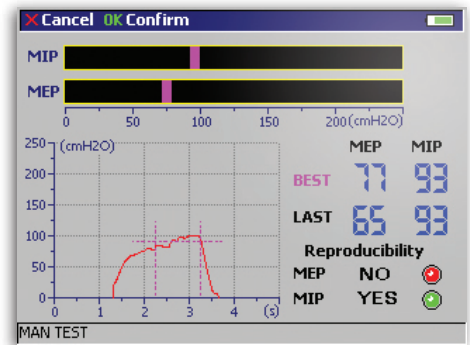
Pony FX screenshot: real-time FVC



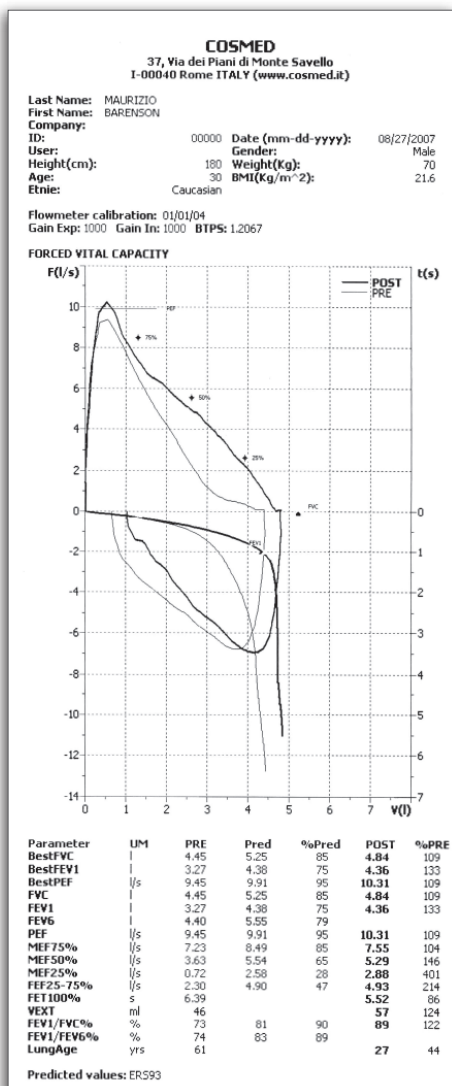
Pony FX screenshot: real-time SpO₂



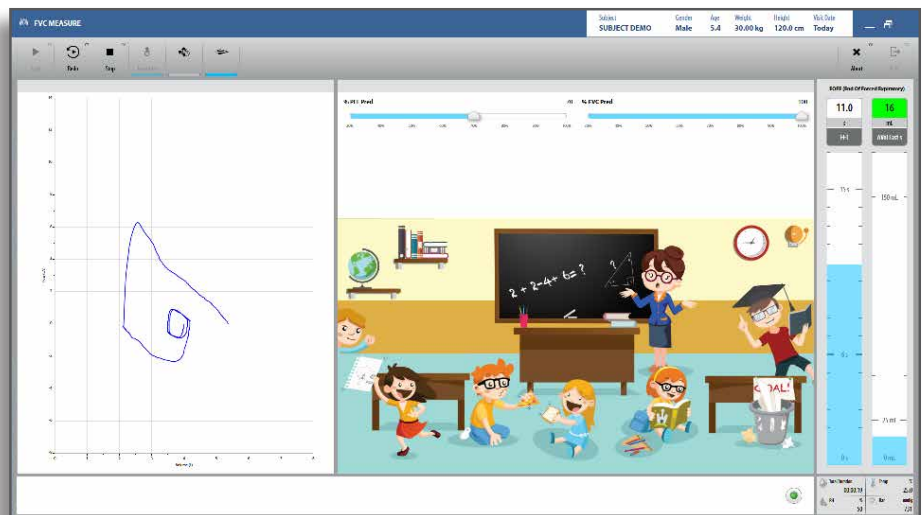
Pony FX screenshot: real-time Rocc



Pony FX screenshot: real-time MIP/MEP



Thermal printout sample (original size 110mm wide):
Forced Vital Capacity (FVC)



Advanced software for data management, real time testing and interpretation directly on PC



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Scientific studies at: www.cosmed.com/bibliography



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To know more



Pony FX

Desktop Spirometer



Technical Specifications

Product	Description	REF
Pony FX	Desktop Spirometer with turbine flowmeter	C09062-01-99
Pony FX MIP/MEP	Desktop Spirometer with turbine flowmeter and respiratory mechanics module	C09062-05-99
Standard packaging		
Pony FX	Pony FX unit, flowmeter, battery charger, adapters, thermal paper, USB cable, carrying case, OMNIA® Software, user manual	
Pony FX MIP/MEP	Pony FX unit, flowmeter, battery charger, MIP/MEP pressure line, rubber mouthpieces, adapters, thermal paper, USB cable, carrying case, OMNIA® Software, user manual	
Measurements		
Spirometry	Forced Vital Capacity (FVC) Pre/Post/Challenge, Slow Vital Capacity (SVC) Pre/Post, Maximum Voluntary Ventilation (MVV)	
Respiratory Mechanics (Pony FX MIP/MEP only)	MIP/MEP	
Hardware		
Dimensions & Weight	198x238x76 mm / 1.2 Kg	
Ports	USB-A, USB-B, RS 232	
Display	Color backlight LCD, 320x240 pixel	
Printer	Built in high speed thermal printer	
Batteries	Rechargeable Li-Ion, 7.4V, 2600 mAh	
Power supply	100-240V, 50/60 Hz	
Flowmeter		
Type	Bidirectional digital turbine	
Resolution	12 mL	
Ventilation Range	0-300 L/min	
Flow Range	0-16 L/s	
Accuracy	± 2% or 20 mL/s	
Resistance	<0.6 cmH ₂ O /L/s @ 14L/s	
Software		
Available languages	English, Chinese (Traditional & Simplified), Czech, Dutch, French, German, Greek, Hebrew (interpretation only), Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Romanian, Russian, Spanish, Turkish	
PC requirements	Windows 7 SP1 (32 bit, 64 bit), Windows 8.x (32 bit, 64 bit), Windows 10 (32 bit, 64bit), Windows 11 (64bit)-, CPU ≥ 2Ghz, RAM ≥ 4GB, HD ≥ 10GB for full installation, Monitor resolution ≥ 1366x768 pixel, ≥2 USB port	
Options/Accessories		
Rocc Module	Airway Resistance (Rocc)	C02650-01-11
Pulse Oximetry	Oximeter (several probes available)	C02600-01-05
Calibration syringe	3L certified syringe for measurements accuracy	C00600-01-11
Consumables		
Antibacterial/Antiviral filter	Single use with oval mouthpiece (50 pcs.)	A-182-300-005
Nose clip	Single use (25 pcs.)	A-662-100-001
Thermal paper	11 m rolls for thermal printer (10 pcs.)	A-196-056-001
Rubber Mouthpiece	Single use for MIP/MEP tests (200 pcs.)	C00568-01-98
Safety & Quality Standards		
MDD (93/42 EEC); FDA 510(k); EN 60601-1 (safety) / EN 60601-1-2 (EMC)		

CE
0476



COSMED
The Metabolic Company



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