ADVANCED

# SPIROLAB®

## Desktop, Stand-alone and PC-based Spirometer, with Oximetry Option

All-in-one Spirometer with 7" display, Embedded Printer and Oximetry option, to carry on the go




MEDICAL INTERNATIONAL RESEARCH

www.spirometry.com

# MAIN features

### REAL-TIME TEST

Spirometry: FVC, VC, IVC, MVV, PRE/POST Bronchodilator comparison
Oximetry (optional): Spot test (SpO2%, Pulse BPM)

### CARRY EVERYWHERE

7" LCD Color Touchscreen Display, Long-lasting rechargeable battery, massive Internal Storage

### COMPLIANCE ATS/ERS 2019

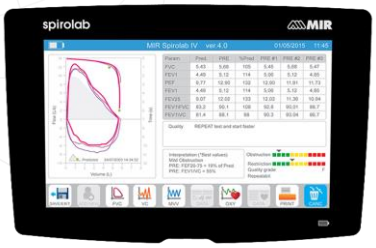
And other Standards including ISO 26782 (for Spirometry), ISO 23747 (for PEF), ISO 80601-2-61 (for Oximetry), and more. CE0476, FDA 510 (k)

### PC CONNECTION AVAILABLE

Real-time test on PC screen, connect with your EHR/EMR, back-up internal memory and more, via USB and Bluetooth

### CALIBRATION SOFTWARE

Available on device, with printable calibration report (no separate software required)



# DISTINCTIVE features

### PREDICTED SETS & VALUES

Large Selection, including GLI, comparison %Pred, Z-score and LLN

### PRINTED EMBEDDED

Thermal printer. Paper size 112mm. Direct external print also available via PC software

### PEDIATRIC INCENTIVE

Real-time animation on display to improve patient compliance during the test

### COVID-19 PREVENTION

Complete Disposable Set with Antiviral filter. Bluetooth connection to test at safety distance

# Always INCLUDED

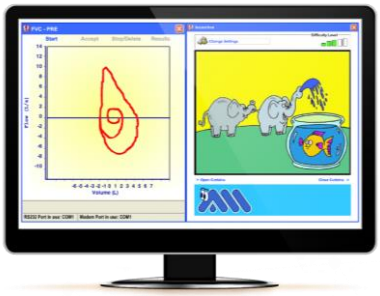
- Carrying case
- Power supply/battery charger
- USB cable
- 1 Roll of thermal printer paper
- Noseclip
- PC Software license

With Oximetry Option:

- Finger Probe

# Compatible SOFTWARE

## winspiroPRO



Pediatric Incentive (PATENTED) to improve patient compliance during the test.

Acceptabilty Messages, Test interpretation and Quality Control Grade according to the latest Spirometry Standards

### MAIN FEATURES

Windows-based solution for Spirometry, Oximetry and Telemedicine.

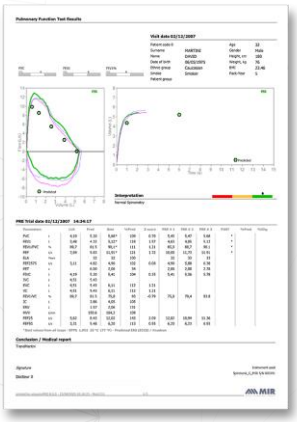
Wide range of predicted sets and values, including GLI Predicted sets, LLN and Z–score.

Embedded EHR/EMR connectivity.

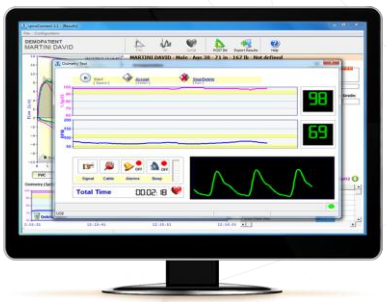
NET VERSION available, share one database between different PC workstations.

### MEDICAL REPORT

Specialized and customizable printout



## spiro Connect



### MAIN FEATURES

Windows-based solution, direct integration with your EHR/EMR.

Real time test include Spirometry and Oximetry

Standardized communication in HL7 or Exchange Protocol.

Select patient info directly from your own EHR/EMR

Spirometry test: FVC-Pre, FVC-Post, VC-Pre
Oximetry Test: SpO2 (%), Pulse (BPM)

### GO-TO-MARKET TOOLKIT

Software Development Kit available for System Integrators and App Developers.
OEM service available for Spirometry and Oximetry.

Learn more about available SDK and OEM

# Compatible TURBINES

| | | Mouthpiece | Turbine Disinfection | Turbine Calibration | Packaging | Antiviral Filter |
|---|---|---|---|---|---|---|
| flowMIR ™ Disposable Turbine |  | Included Disposable | Not required | Not required | Individually sealed: 60 or 10 units / box | Available Disposable |
| Reusable Turbine |  | Required, Not Included | Required | Required | 1 unit in Carton box | Required Disposable |

PLAY VIDEO

SCIENTIFIC PUBLICATIONS

# TECHNICAL datasheet

## PRODUCT CODES - Spirolab Configurations

911080E0 – Spirometer • 911080E1 - Spirometer with reusable turbine
911081E0 - Spirometer + Oximeter • 911081E1 - Spirometer + Oximeter with reusable turbine

### Technical specification

| | |
|---|---|
| Width | 220 mm |
| Length | 210 mm |
| Thickness | 51 mm |
| Weight | 1450 g (battery pack included) |

Sensors

miniflowmeter (code 900595)
for reusable and disposable turbine
dimension (∅ 30 mm, 42 mm)

Reusable soft, adult, MIR sensor for oximetry tests (code 919024) only spirolab code 911081

| | |
|---|---|
| Power supply | Rechargeable battery and mains |
| power | Ni-MH, 6 elements |
| Current capacity | 4500 mAh |
| Consumption | average 250 mA |
| Backup battery voltage | none |
| Batteries charger | Output voltage=12 V, current=1A, compliant with EN 60601-1 |
| Autonomy | ~10 hours |
| Connectivity | USB 2.0, Bluetooth® 2.1 |
| Display | 7 inch colour touch screen LCD |
| Display | with 800x480 resolution |
| Keyboard | absent, touchscreen |
| Mouthpieces | Ø 30 mm (1.18 inch) |
| Type of electrical Protection | Internally powered Class II while charging battery |
| Safety level for shock hazard | Type BF Apparatus |
| Conditions of use | Apparatus for continuous use |

| | | |
|---|---|---|
| Storage conditions | Temperature: | MIN -40 °C, MAX +70 °C |
| | Humidity: | MIN 10% RH; MAX 95%RH |
| Transport conditions | Temperature: | MIN -40 °C, MAX +70 °C |
| | Humidity: | MIN 10% RH; MAX 95%RH |
| Operating conditions | Temperature: | MIN + 10 °C, MAX + 40 °C |
| | Humidity: | MIN 10% RH, MAX 95%RH |

| | |
|---|---|
| Applied norms | Electrical Safety EN 60601-1<br>Electro Magnetic Compatibility EN 60601-1-2 |
| Degree of protection against water penetration | IPX1 appliance protected against water leaks |

### Codes and equipments

| | |
|---|---|
| 911080E0 | spiro |
| 911080E1 | spiro with reusable turbine |
| 911080E2 | spiro with 120 FlowMir |
| 911081E0 | spiro+oxy |
| 911081E1 | spiro+oxy with reusable turbine |
| 911081E2 | spiro+oxy with 120 FlowMir |

### Spirometry

| | |
|---|---|
| Flow sensor | bi-directional digital turbine |
| Volume rate | 10 L |
| Flow range | ±16L/s |
| Volume accuracy | ±2.5% or 50 mL |
| Flow accuracy | ±5% or 200 mL/s |
| Dynamic resistance | <0.5 cm H2O/L/s |
| Temperature sensor | semiconductor (0-45°C) |
| Test available | FVC, VC, IVC, MVV, PRE-POST |
| Measured parameters | FVC, FEV1, FEV1/FVC%, FEV1/PEF, FEV1/VC, FEV1/FEF0.5, DTPEF, FEV 0.5, FEV0.5/FVC, FEV0.75, FEV0.75/FVC, FEV2, FEV2/FVC, FEV3, FEV3/FVC, FEV6, FEV1/FEV6, PEF, FEF25, FEF50, FEF75, FEF2575, FEF7585, FET, Vext, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC, FIF25, FIF50, FIF75, R50, MVVcal, PIF, IRV, VC, EVC, IVC, IC, ERV, IRV, FEV1/VC, TV, VE, RR, ti, te, ti/t-tot, TV/ti, MVV |
| Memory capacity | Up to 10000 tests |

### Oximetry (on request)

| | |
|---|---|
| Measurement method | Red and infrared absorption |
| SpO2 range | 0-99% |
| SpO2 accuracy | ± 2% between 70-99% SpO2 |
| Average number of heart beats for the %SpO2 calculation | 8 beats |
| Pulse Rate range | 18-300 BPM |
| Pulse Rate accuracy | ± 2BPM or 2% whichever is greater |
| Average interval for the calculation of cardiac pulse | 8 seconds |
| Signal quality indication | 0 - 8 segments on display |
| Test available | spot |
| Measured parameters | SpO2% min, max, average<br>BPM min, max, average<br>Test duration<br>% Bradycardia Duration (<40 BPM)<br>% Tachycardia Duration (>120 BPM)<br>% of Time with SpO2 ≤ 90% (T90%, T89%), T5 |
| Memory capacity | about 500 hours oximetry |

### Certificates & Registrations

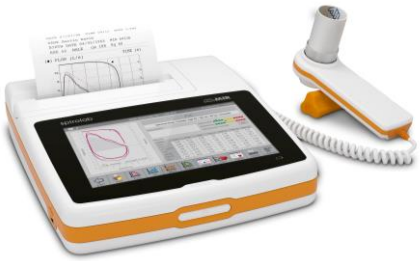
| | |
|---|---|
| CE 0476 | MED 9826 |
| FDA 510 (k) | K 052140 |
| Health Canada | 71191 (class II) |
| CND code | Z12150102 (spiro)<br>Z1203020408 (spiro + oxy) |
| GMDN code | 46906 (spiro), 45607 (spiro + oxy) |
| Ministry of Health | 1272475/R (spiro)<br>1272476/R (spiro + oxy)<br>1645455/R (spiro) |

MIR
MEDICAL INTERNATIONAL RESEARCH

ITALY
MIR Head Office
Via del Maggiolino, 125
00155 Roma
Tel. +39 06 22 754 777
Fax +39 06 22 754 785
Mir.spirometry.com

USA
MIR USA, Inc.
5462 S. Westridge Drive
New Berlin, WI 53151
Phone +1 (262) 565-6797
Fax +1 (262) 364-2030

FRANCE
MIR Local Office
Jardin des Entreprises,
290, Chemin de Saint Dionisy
30980 LANGLADE (France)
Phone +33 (0)4 66 37 20 68
Fax +33 (0)4 84 25 14 32



## Technical specification

| | |
|---|---|
| **Width** | 220 mm |
| **Length** | 210 mm |
| **Thickness** | 51 mm |
| **Weight** | 1450 g (battery pack included) |

**Sensors**

miniflowmeter (code 900595)
for reusable and disposable turbine
dimension (∅ 30 mm, 42 mm)

Reusable soft, adult, MIR sensor for oximetry tests (code 919024) only for spirolab code 911081

| | |
|---|---|
| **Power supply** | Rechargeable battery and mains power Ni-MH, 6 elements |
| **Current capacity** | 4500 mAh |
| **Consumption** | average 250 mA |
| **Backup battery voltage** | none |
| **Batteries charger** | Output voltage=12 V, current=1A, compliant with EN 60601-1 |
| **Autonomy** | ~10 hours |
| **Connectivity** | USB 2.0, Bluetooth® 2.1 |
| **Display** | 7 inch colour touch screen LCD Display with 800x480 resolution |
| **Keyboard** | absent, touchscreen |
| **Mouthpieces** | Ø 30 mm (1.18 inch) |
| **Type of electrical protection** | Internally powered<br>Class II while charging battery |
| **Safety level for shock hazard** | Type BF Apparatus |
| **Conditions of use** | Apparatus for continuous use |
| **Storage conditions** | Temperature: MIN -40 °C, MAX +70 °C<br>Humidity: MIN 10% RH; MAX 95%RH |
| **Transport conditions** | Temperature: MIN -40 °C, MAX +70 °C<br>Humidity: MIN 10% RH; MAX 95%RH |
| **Operating conditions** | Temperature: MIN + 10 °C, MAX + 40 °C<br>Humidity: MIN 10% RH, MAX 95%RH |
| **Applied norms** | Electrical Safety EN 60601-1<br>Electro Magnetic Compatibility EN 60601-1-2 |
| **Degree of protection against water penetration** | IPX1 appliance protected against water leaks |

## Codes and equipments

| | |
|---|---|
| **911080E0** | spiro |
| **911080E1** | spiro with reusable turbine |
| **911080E2** | spiro with 120 FlowMir |
| **911081E0** | spiro+oxy |
| **911081E1** | spiro+oxy with reusable turbine |
| **911081E2** | spiro+oxy with 120 FlowMir |

## Spirometry

| | |
|---|---|
| **Flow sensor** | bi-directional digital turbine |
| **Volume rate** | 10 L |
| **Flow range** | ±16L/s |
| **Volume accuracy** | ±2.5% or 50 mL |
| **Flow accuracy** | ±5% or 200 mL/s |
| **Dynamic resistance** | <0.5 cm H2O/L/s |
| **Temperature sensor** | semiconductor (0-45°C) |
| **Test available** | FVC, VC, IVC, MVV, PRE-POST |
| **Measured parameters** | FVC, FEV1, FEV1/FVC%, FEV1/PEF, FEV1/VC, FEV1/FEF0.5, DTPEF, FEV 0.5, FEV0.5/FVC, FEV0.75, FEV0.75/FVC, FEV2, FEV2/FVC, FEV3, FEV3/FVC, FEV6, FEV1/FEV6, PEF, FEF25, FEF50, FEF75, FEF2575, FEF7585, FET, Vext, ELA, EVOL, FIVC, FIV1, PIF, FIV1/FIVC, FIF25, FIF50, FIF75, R50, MVVcal, PIF, IRV, VC, EVC, IVC, IC, ERV, IRV, FEV1/VC, TV, VE, RR, ti, te, ti/t-tot, TV/ti, MVV |
| **Memory capacity** | Up to 10000 tests |

## Oximetry (on request)

| | |
|---|---|
| **Measurement method** | Red and infrared absorption |
| **SpO2 range** | 0-99% |
| **SpO2 accuracy** | ± 2% between 70-99% SpO2 |
| **Average number of heart beats for the %SpO2 calculation** | 8 beats |
| **Pulse Rate range** | 18-300 BPM |
| **Pulse Rate accuracy** | ± 2BPM or 2% whichever is greater |
| **Average interval for the calculation of cardiac pulse** | 8 seconds |
| **Signal quality indication** | 0 - 8 segments on display |
| **Test available** | spot |
| **Measured parameters** | SpO2% min, max, average<br>BPM min, max, average<br>Test duration<br>% Bradycardia Duration (<40 BPM)<br>% Tachycardia Duration (>120 BPM)<br>% of Time with SpO2 ≤ 90% (T90%, T89%), T5 |
| **Memory capacity** | about 500 hours oximetry |

## Certificates & Registrations

| | |
|---|---|
| **CE 0476** | MED 9826 |
| **FDA 510 (k)** | K 052140 |
| **Health Canada** | 71191 (class II) |
| **CND code** | Z12150102 (spiro)<br>Z1203020408 (spiro + oxy) |
| **GMDN code** | 46906 (spiro), 45607 (spiro + oxy) |
| **Ministry of Health** | 1272475/R (spiro)<br>1272476/R (spiro + oxy)<br>1645455/R (spiro) |

CERTIFICATE

| | | | |
|---|---|---|---|
| Reg. Number | 620 - M | Valid From | 2021-02-01 |
| First issue date | 2009-02-28 | Last change date | 2021-02-01 |
| Valid until | 2024-02-15 | | |
| Previous expiry date | | | |

Quality Management System Certificate

## ISO 13485:2016

We certify that the Quality Management System of the Organization:

# MIR S.R.L. - MEDICAL INTERNATIONAL RESEARCH

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

Design, manufacturing and sales of medical devices and accessories for lung function analysis.

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.

*The date of issuance of this certificate is the date of first issue by another accredited body*
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

**MIR S.R.L. - MEDICAL INTERNATIONAL RESEARCH**
**Registered Headquarters**
- Via del Maggiolino, 125 00155 Roma Italia

**Certified Sites**
- Via del Maggiolino, 125 00155 Roma Italia

SGQ N° 007A

CERTIFICATE

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 9826 | Revisione / *Revision* | 19 |
| Primo rilascio / *First issue date* | 1998-06-11 | Valido da / *Valid from* | 2018-02-05 |
| Scadenza / *Valid until* | 2023-02-04 | Ultima modifica / *Last change date* | 2021-05-20 |



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:*

# MIR S.r.l. - MEDICAL INTERNATIONAL RESEARCH

**Sede Legale e Operativa** / *Registered and Operational Headquarter:*
Via del Maggiolino, 125
00155 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:*

Consumabili per spirometria / *Consumables for spirometry*
Dispositivo medico per la rilevazione della fibrillazione atriale da ECG a singola derivazione / *Medical device for the detection of atrial fibrillation from a single-lead ECG*
Ossimetri / *Oximeters*
Spirometri / *Spirometers*
Spirometri con ossimetria / *Spirometers with oximetry*
Turbine monouso con boccaglio in carta / *Disposable turbines with cardboard mouthpiece*

Kiwa Cermet Italia S.p.A.
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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.kiwacermet.it

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* 02/04/2021

Chief Operating Officer
*Giampiero Belcredi*

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:20/05/2021 10:24:50

Organismo Notificato n. 0476
*Notified Body nr. 0476*

CERTIFICATE

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 9826 | Revisione / *Revision* | 19 |
| Primo rilascio / *First issue date* | 1998-06-11 | Valido da / *Valid from* | 2018-02-05 |
| Scadenza / *Valid until* | 2023-02-04 | Ultima modifica / *Last change date* | 2021-05-20 |



## Allegato tecnico al Certificato/
## *Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Consumabili per spirometria / *Consumables for spirometry*

**Classe di rischio** / *Risk class:*
II a

**Codice NANDO** / *NANDO codes:*
MD 1302

**Marca** / *Brandname:*
MIR

**Modello** / Model:

Boccagli in plastica / Plastic mouthpieces

**Codici** / Codes:

910305

**Tipologia /** *Medical Devices:*
Dispositivo medico per la rilevazione della fibrillazione atriale da ECG a singola derivazione / *Medical device for the detection of atrial fibrillation from a single-lead ECG*

**Classe di rischio** / *Risk class:*
II a

**Codice NANDO** / *NANDO codes:*
MD 1302, MDS 7010

**Marca** / *Brandname:*
MIR

**Modello** / Model:

Cardionica

**Codici** / Codes:

912000xx

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E-mail: info@kiwacermet.it
www.kiwacermet.it

**Chief Operating Officer**
*Giampiero Belcredi*

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:20/05/2021 10:25:10

CE
Organismo Notificato n. 0476
*Notified Body nr. 0476*

CERTIFICATE

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 9826 | Revisione / *Revision* | 19 |
| Primo rilascio / *First issue date* | 1998-06-11 | Valido da / *Valid from* | 2018-02-05 |
| Scadenza / *Valid until* | 2023-02-04 | Ultima modifica / *Last change date* | 2021-05-20 |



## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Ossimetri / *Oximeters*

**Classe di rischio** / *Risk class:*
II a

**Codice NANDO** / *NANDO codes:*
MD 1302

**Marca** / *Brandname:*
MIR

**Modello** / Model:
Spirodoc

**Codici** / Codes:
910606xx - 9106061x

**Tipologia /** *Medical Devices:*
Spirometri / *Spirometers*

**Classe di rischio** / *Risk class:*
II a

**Codice NANDO** / *NANDO codes:*
MD 1301

**Modello** / Model:
AsthmaTuner

**Codici** / Codes:
911115xx

**Modello** / Model:
cSpirometer

**Codici** / Codes:
911111xx

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E-mail: info@kiwacermet.it
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**Chief Operating Officer**
*Giampiero Belcredi*

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:20/05/2021 10:25:41

CE
Organismo Notificato n. 0476
*Notified Body nr. 0476*

CERTIFICATE

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| Scadenza / *Valid until* | 2023-02-04 | Ultima modifica / *Last change date* | 2021-05-20 |



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*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Spirometri / *Spirometers*

**Modello** / Model:
mSpirometer
**Codici** / Codes:
911110xx

**Modello** / Model:
Spirobank Smart
**Codici** / Codes:
911105xxx, 911106xx

**Marca** / *Brandname:*
MIR
**Modello** / Model:
MiniSpir
**Codici** / Codes:
911000xx - 911006xx

**Modello** / Model:
MiniSpir Light
**Codici** / Codes:
911001 - 911003

**Modello** / Model:
Spirobank II
**Codici** / Codes:
911020xx - 911021xx - 911028xx

**Modello** / Model:
Spirodoc
**Codici** / Codes:
910600xx - 9106001xx

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**Chief Operating Officer**
*Giampiero Belcredi*

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:20/05/2021 10:26:22

**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

CERTIFICATE

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| Reg. Numero / *Reg. Number* | MED 9826 | Revisione / *Revision* | 19 |
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**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Spirometri / *Spirometers*

**Marca** / *Brandname:*
MIR

**Modello** / Model:
Spirolab

**Codici** / Codes:
911080xx

**Modello** / Model:
Spirotel

**Codici** / Codes:
9107xxx - 9107100_Q

**Codice NANDO** / *NANDO codes:*
MD 1301, MDS 7010

**Modello** / Model:
Smart One

**Codici** / Codes:
911100xx

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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.kiwacermet.it

Chief Operating Officer
*Giampiero Belcredi*

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:20/05/2021 10:26:42

Organismo Notificato n. 0476
*Notified Body nr. 0476*

CERTIFICATE

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 9826 | Revisione / *Revision* | 19 |
| Primo rilascio / *First issue date* | 1998-06-11 | Valido da / *Valid from* | 2018-02-05 |
| Scadenza / *Valid until* | 2023-02-04 | Ultima modifica / *Last change date* | 2021-05-20 |



## Allegato tecnico al Certificato/
## *Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Spirometri con ossimetria / *Spirometers with oximetry*

**Classe di rischio** / *Risk class:*
II a

**Codice NANDO** / *NANDO codes:*
MD 1302

**Marca** / *Brandname:*
MIR

**Modello** / Model:

Spirodoc

**Codici** / Codes:

910610xx - 9106101xx

**Codice NANDO** / *NANDO codes:*
MD 1302, MDS 7010

**Marca** / *Brandname:*
MIR

**Modello** / Model:

MiniSpir

**Codici** / Codes:

911010xx

**Modello** / Model:

Spirobank II

**Codici** / Codes:

911025xx - - 911029xx

**Modello** / Model:

Spirolab

**Codici** / Codes:

911081xx

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Fax +39.051.763.382
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www.kiwacermet.it

**Chief Operating Officer**
*Giampiero Belcredi*

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:20/05/2021 10:27:06

**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

CERTIFICATE

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|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 9826 | Revisione / *Revision* | 19 |
| Primo rilascio / *First issue date* | 1998-06-11 | Valido da / *Valid from* | 2018-02-05 |
| Scadenza / *Valid until* | 2023-02-04 | Ultima modifica / *Last change date* | 2021-05-20 |



## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Spirometri con ossimetria / *Spirometers with oximetry*

**Marca** / *Brandname:*
MIR

**Modello** / Model:
Spirotel

**Codici** / Codes:
9107xx1

**Codice NANDO** / *NANDO codes:*
MDS 7010, MD 1302

**Modello** / Model:
Smart One Oxi

**Codici** / Codes:
911120xx

**Modello** / Model:
Spirobank Oxi

**Codici** / Codes:
911125xx

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Chief Operating Officer
*Giampiero Belcredi*

Firmato digitalmente da:BELCREDI GIAMPIERO
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Organismo Notificato n. 0476
*Notified Body nr. 0476*

CERTIFICATE

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|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 9826 | Revisione / *Revision* | 19 |
| Primo rilascio / *First issue date* | 1998-06-11 | Valido da / *Valid from* | 2018-02-05 |
| Scadenza / *Valid until* | 2023-02-04 | Ultima modifica / *Last change date* | 2021-05-20 |



## Allegato tecnico al Certificato/
## *Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia /** *Medical Devices:*
Turbine monouso con boccaglio in carta / *Disposable turbines with cardboard mouthpiece*

**Classe di rischio** / *Risk class:*
II a

**Codice NANDO** / *NANDO codes:*
MD 0106

**Marca** / *Brandname:*
MIR

**Modello** / Model:

FlowMir

**Codici** / Codes:

910004

**Modello** / Model:

Nuvoair

**Codici** / Codes:

910007

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**
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Data:20/05/2021 10:27:49

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**Organismo Notificato n. 0476**
*Notified Body nr. 0476*