



# Spirolab



**All-in-one Desktop Spirometer**  
for rapid and comprehensive reporting

# Supported tests

**Spirometry:** FVC, VC, MVV, PRE/POST bronchodilator comparison

**Oximetry (optional):** Spot test (SpO2%, BPM)

## Key features

### All-in-one

Complete spirometer, all-in-one touchscreen and integrated printer for testing without the need for a computer

### Calibration

Available on device, with calibration report printable by the instrument

### 7" colour touchscreen

Intuitive interface and clear data display

### SpO2% Sensor

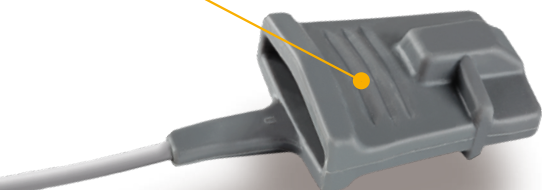
Oximetry sensor to detect blood oxygen saturation

### Connection to external Postscript Printer

### Integrated thermal printer

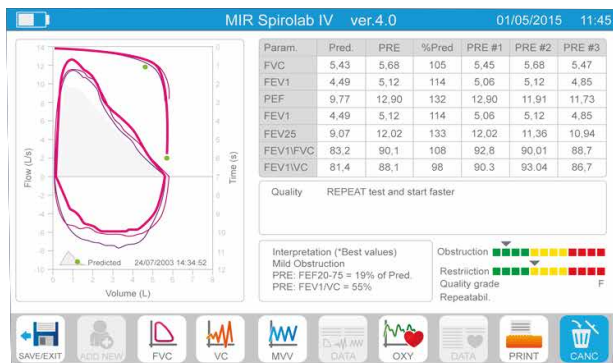
Customizable print and detailed immediate test reports. 80<120 prints with a single roll\*.

(Paper size 112 mm; Paper weight 56g +/- 4 gr/m2)



\*Using non-original MIR paper rolls or heavier than indicated can irreparably damage the printer

## Real-time tests



## Integrated temperature sensor

Automatic BTPS Conversion

## Long-lasting rechargeable battery

Long-lasting rechargeable lithium battery for extended autonomy in Stand Alone mode

## Large internal memory

Storage up to 10,000 spirometric tests or 500 hours of oximetry

## Pediatric incentive



## Predicted values

Wide selection of predicted values including GLI, ERS and others, directly on the device and in PC mode

## EMR/EHR connectivity

Integration via **MIR Spiro** software with EMR/EHR (in HL7, GDT, FHIR, EXCHANGE PROTOCOL)

# Compatible turbines

		Mouthpiece	Turbine disinfection	Turbine calibration	Packaging	Antiviral filter
FlowMIR® disposable turbine		Disposable included	Not required	Not required	Individually packaged: packs of 60 pieces	Optional
Reusable turbine		Required, not included	Required	Required	Pack of 1 unit	Recommended by ATS

# How to use

Spirolab works both in **Stand Alone** mode and connected to **PC via USB**

## MIR Spiro software

- \\ Comprehensive software for spirometry and oximetry
- \\ Designed to be integrated with EMR/EHR
- \\ Complies with the latest ATS/ERS guidelines
- \\ Available for desktop and laptop use
- \\ MacOS and Windows

All MIR professional devices work with **MIR Spiro** software, **the latest generation software** for spirometry and oximetry.



## Platinum Card

To subscribe to a Platinum subscription plan it is necessary to **have the MIR Spiro Platinum Card.**





# Measured parameters

	From MIR Spiro software via connection to the device	From device in Stand Alone mode
<b>Spirometry</b>	FVC, FEV1, PEF, FEF75, FEF25-75, FET, FEV1/FVC, FEV6, FEV1/FEV6, FEF25, FEF50, FIVC, FEV1/VC, ELA, MVV(cal), Time to PEF, FEV0.5, FEV0.5/FVC, FEV0.75, FEV0.75/FVC, FEF75-85, Extr. Vol, VC, EVC, IVC, IC, VC, ERV FEV3, FIV1, FIV1/FIVC, PIF, FEV3/FVC, PIF, FEV2, FEV2/FVC, FIF25, FIF50, FIF75, R50, FEV1/PEF (EI), FEV1/FEV0.5 (RFEV), TV, VE, RR, tI	VC, FEV1, FEV1/ FVC, FEV1/VC, PEF, FEF25, FEF50, FEF75, FEF25-75, FEF75-85, ELA, extrapolated Vol, FET, Time to PEF, FEV0.5, FEV0.5/FVC, FEV0.75, FEV0.75/ FVC,FEV2, FEV2/ FVC, FEV3, FEV3/ FVC, FEV6, FEV1/ FEV6, FEV1/PEF, FEV1/FEV0. 5, FIVC, FIV1, FIV1/FIVC, PIF, FIF25, FIF50, FIF75, FEF50/FIF50, VC, IVC, IC, ERV, IRV, Rf, VE, VT, tI, tE, VT/tI, tE/tTOT, MVV (measured), MVV (calculated)
<b>Oximetry (optional)</b>	SpO2% [Baseline, Min, Max, Mean], Wrist Rate [Baseline, Min, Max, Mean], T90, T89, T88, T5, Index [12s], SpO2% Events, Wrist Rate Events [bradycardia, tachycardia], Tot Time, Measured Time	SpO2% [Baseline, Min, Max, Mean], Wrist Rate [Baseline, Min, Max, Mean], T90, T89, T88, T5, Index [12s], SpO2% Events, Wrist Rate Events [bradycardia, tachycardia], Tot Time, Measured Time

# Datasheet

code 911080xx (spiro) code 911081xx (spiro+oxy)

Size	220 x 210 x 51 mm
Weight	1450 g (battery pack included)
Sensors	<ul style="list-style-type: none"> <li>· For reusable and disposable miniflowmeter turbines (code 910595)</li> <li>· For spirolab code 911081 only Reusable soft adult sensor for oximetry test (code 919024)</li> </ul>
Power supply	Ni-MH rechargeable battery pack, 6 elements
Current	4500 mAh
Consumption	medium 250 mA
Backup battery voltage	absent
Charge Batteries	output voltage=12 V, current=1A, compliant with EN 60601-1
Autonomy	~ 10 hours
Connectivity	USB 2.0, Bluetooth® 5
Display	7 inch colour touchscreen resolution 800x480 pixels LCD
Keyboard	absent, touchscreen
Mouthpiece	Ø 30 mm (1.18 inches)
Type of electrical protection	Internally powered Class II while battery is charging
Safety level due to shock hazard	Type BF device
Terms of use	Device for continuous use
Storage conditions	Temp: MIN -40°C, MAX+60°C Humidity: MIN 10% RH; MAX 95%RH
Transport conditions	Temp: MIN -40°C, MAX +60°C Humidity: MIN 10% RH; MAX 95%RH
Operating conditions	Temp: MIN +10°C, MAX +40°C Humidity: MIN 10% RH, MAX 95%RH
Degree of protection against water penetration	IPX1
<b>Spirometry</b>	
Sensor	two-way digital turbine
Volume range	10 L
Flow range	±16L/s
Volume accuracy	±2.5%o50mL
Flow accuracy	±5% or 200 mL/s
Dynamic resistance	<0.5 cm H2O/L/s
Temperature sensor	semiconductor (0-45°C)

<b>Available tests</b>	FVC, VC, IVC, MVV, PRE-POST
<b>Measured parameters</b>	FVC, FEV1, FEV1/FVC%, FEV1/PEF, FEV1/VC, FEV1/FEV0.5, PEF Time, 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
<b>Memory capacity</b>	more than 10,000 tests
<b>Oximetry (on request)</b>	
<b>Measurement method</b>	Infrared absorption
<b>SpO2% Range</b>	0-99%
<b>Accuracy of SpO2%</b>	± 2% between 70-99% SpO2%
<b>Average number of beats for SpO2% calculation</b>	8 beats
<b>Cardiac pulse range</b>	18-300 BPM
<b>Cardiac pulse accuracy</b>	± 2BPM or 2% the greater of the two
<b>Mean interval for calculation of heartbeat</b>	8 seconds
<b>Signal quality indication</b>	0 - 8 segments on screen
<b>Test available</b>	spot
<b>Measured parameters</b>	SpO2% min, max, average Min, Max, Avg BPM Test duration % Duration of bradycardia (<40 BPM) % Duration of tachycardia (>120 BPM) % Time with %SpO2 ≤ 90% (T90%, T89%), T5
<b>Memory capacity</b>	about 500 hours of oximetry

<b>Certificates and registrations</b>	
<b>CE 0476</b>	MDR 2017/745
<b>FDA 510 (k)</b>	K 052140
<b>Health Canada</b>	71191 (Class II)
<b>EMDN liv.4</b>	Z121501
<b>CND Code</b>	Z12150102
<b>GMDN Code</b>	46906 (spiral), 45607 (spiro + oxy)
<b>Ministry of Health</b>	2494321/R (code 9110801I) 2494344/R (code 9110811I) 2494441/R (code 9110801O) 2494453/R (code 9110811O)
<b>Applicable regulations</b>	Electrical Safety IEC 60601-1 Electro Magnetic Compatibility EN 60601-1-2 ISO 80601-2-61:2017 ISO 26782: 2009 ISO 23747: 2015 ATS/ERS:2005, 2019(update) IEC 60601-1-6:2010 IEC 60601-1-8:2006+ AMD1:2012 IEC 60601-1-9:2007+AMD1:2013 IEC 62304:2006 + A1:2015 ISO 10993-1:2018 Directive 2014/53/EU RED IEC 62311:2019 EN 62311:2020

## Compliance with guidelines and standards

**Spirometry:** ATS/ERS 2005 + update to 2019;

ISO 23747: 2015; ISO 26782: 2009

**Oximetry:** ISO 80601-2-61:2017

## ITALY

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[mirbrazil@spirometry.com](mailto:mirbrazil@spirometry.com)







# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
C642759

Initial certification date:  
16 January 2024

Valid:  
16 February 2024 – 15 February 2027

This is to certify that the management system of  
**MIR Medical International Research S.P.A.**  
Viale Luigi Schiavonetti, 270 - 00173 Rome (RM) - Italy

has been found to conform to the Quality Management System standard:  
**ISO 9001:2015**

This certificate is valid for the following scope:  
**Design, manufacturing and sales of medical devices and accessories for lung function and cardiovascular system and analysis (IAF 19, 14, 29)**

Place and date:  
Vimercate (MB), 01 February 2024



SGQ N° 003 A  
SGA N° 003 D  
SGE N° 007 M  
SCR N° 004 F

EMAS N° 009 P  
PRD N° 003 B  
PRS N° 094 C  
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento  
SGQ, SGA, PRD, PRS, ISP, GIIG, LAB e LAT, di MLA IAF  
per gli schemi di accreditamento SGQ, SGA, SSI, FSM  
e PRD e di MRA ILAC per gli schemi di accreditamento  
LAB, MED, LAT e ISP

For the issuing office:  
**DNV - Business Assurance**  
Via Energy Park, 14, - 20871 Vimercate (MB) -  
Italy

**Claudia Baroncini**  
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Business Assurance Italy S.r.l., Via Energy Park, 14 - 20871 Vimercate (MB) - Italy - TEL: +39 68 99 905. www.dnv.it



# MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:  
C642756

Initial certification date:  
16 January 2024

Valid:  
16 February 2024 – 15 February 2027

This is to certify that the management system of  
**MIR Medical International Research S.P.A.**  
Viale Luigi Schiavonetti, 270 - 00173 Rome (RM) - Italy

has been found to conform to the Quality Management System standard:  
**ISO 13485:2016**

This certificate is valid for the following scope:  
**Design, manufacturing and sales of medical devices and accessories for lung function and cardiovascular system and analysis**

Place and date:  
Vimercate (MB), 01 February 2024



SGQ N° 003 A  
SGA N° 003 D  
SGE N° 007 M  
SCR N° 004 F

EMAS N° 009 P  
PRD N° 003 B  
PRS N° 094 C  
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento  
SGQ, SGA, PRD, PRS, ISP, GIIG, LAB e LAT, di MLA IAF  
per gli schemi di accreditamento SGQ, SGA, SSI, FSM  
e PRD e di MRA ILAC per gli schemi di accreditamento  
LAB, MED, LAT e ISP

For the issuing office:  
**DNV - Business Assurance**  
Via Energy Park, 14, - 20871 Vimercate (MB) -  
Italy

**Claudia Baroncini**  
Management Representative



Reg. Numero / Reg. Number	MDR 00020-A	Revisione / Revision	1
Primo rilascio / First issue date	2023-02-16	Valido da / Valid from	2023-02-16
Scadenza / Valid until	2028-02-15	Ultima modifica / Last change date	2023-07-10
Data Scadenza Precedente / Previous Expiry			

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## Certificato UE del Sistema di Gestione della Qualità *EU Quality Management System Certificate*

Kiwa Cermet Italia certifica che, sulla base dei risultati delle valutazioni effettuate, il Sistema di Gestione della Qualità dell'Organizzazione:

Kiwa Cermet Italia certifies that, on the basis of the assessment carried out, the Quality Management System of the Organization:

### MIR - MEDICAL INTERNATIONAL RESEARCH S.p.A.

**Operatore economico / Economic operator:** Fabbrikante

**SRN:** IT-MF-000014026

**Sede Legale e Operativa / Legal and Operational Headquarters**

Viale Luigi Schiavonetti 270 - 00173 Roma (RM) - Italia

E' conforme ai requisiti applicabili del Regolamento (UE) 2017/745, Allegato IX capo I e III, per le seguenti tipologie di dispositivi:

*Is in compliance with the applicable requirements of Regulation (EU) 2017/745, Annex IX Chapter I and III, for the following devices types:*

Z120503 - Elettrocardiografi / *Electrocardiographs*

Z1203020408 - PULSOSSIMETRI / *PULSE OXIMETERS*

Z12150102 - Spirometri per picco di flusso / *Peak flow spirometers*

Z12150180 - Strumentazione per spirometria - accessori hardware / *Spirometry instruments - hardware accessories*

CERTIFICATE

**Kiwa Cermet Italia S.p.A.**  
Società con socio unico, soggetta  
all'attività di direzione e coordinamento  
di Kiwa Italia Holding Srl

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[www.kiwa.it](http://www.kiwa.it)

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

**Presidente / President**  
*Giampiero Belcredi*

Firmato digitalmente da: BELCREDI GIAMPIERO  
Data: 10/07/2023 15:59:30



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Data Scadenza Precedente / Previous Expiry			

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

### Identificazione dei Dispositivi / Devices identification:

#### Tipologia / Type:

Z120503 - Elettrocardiografi / *Electrocardiographs*

#### Nome / Name:

Elettrocardiografo / *Electrocardiograph*

#### Modello / Model:

Cardionica

#### Nome commerciale / Brandname:

Cardionica

#### Classe di rischio / Risk class:

II a

#### Tipologia / Type:

Z1203020408 - PULSOSSIMETRI / *PULSE OXIMETERS*

#### Nome / Name:

Ossimetro / *Oximeter*

#### Modello / Model:

Spirodoc

#### Nome commerciale / Brandname:

Spirodoc

#### Classe di rischio / Risk class:

II a

#### Tipologia / Type:

Z12150102 - Spirometri per picco di flusso / *Peak flow spirometers*

# CERTIFICATE

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Organismo Notificato n. 0476  
Notified Body nr. 0476

**CERMET**

MOD P022A2\_MED\_MDR rev. 2

Presidente / President  
*Giampiero Belcredi*

Firmato digitalmente da: BELCREDI GIAMPIERO  
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## Allegato tecnico al Certificato Technical sheet enclosed to the Certificate

### Identificazione dei Dispositivi / Devices identification:

**Nome / Name:**

Spirometro / *Spirometer*

**Modello / Model:**

Spirobank Smart; mSpirometer; AsthmaTuner; Smart One; cSpirometer

**Nome commerciale / Brandname:**

Spirobank Smart; mSpirometer; AsthmaTuner; Smart One; cSpirometer

**Classe di rischio / Risk class:**

II a

**Nome / Name:**

Spirometro / *Spirometer*

**Modello / Model:**

MiniSpir; MiniSpir Light POST BD

**Nome commerciale / Brandname:**

MiniSpir; MiniSpir Light POST BD

**Classe di rischio / Risk class:**

II a

**Nome / Name:**

Spirometro con o senza ossimetro / *Spirometer with or without oximeter*

**Modello / Model:**

Spirolab

**Nome commerciale / Brandname:**

Spirolab

**Classe di rischio / Risk class:**

II a

**Nome / Name:**

Spirometro con o senza ossimetro / *Spirometer with or without oximeter*

Kiwa Cermet Italia S.p.A.  
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Presidente / President

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

### Identificazione dei Dispositivi / *Devices identification:*

**Modello / Model:**

Spirodoc

**Nome commerciale / Brandname:**

Spirodoc

**Classe di rischio / Risk class:**

II a

**Nome / Name:**

Spirometro con o senza ossimetro // *Spirometer with or without oximeter*

**Modello / Model:**

Spirobank II; Spirobank II with Bluetooth smart

**Nome commerciale / Brandname:**

Spirobank II; Spirobank II with Bluetooth smart

**Classe di rischio / Risk class:**

II a

**Nome / Name:**

Spirometro con ossimetro / *Spirometer with oximeter*

**Modello / Model:**

Spirobank Oxi; Smart One Oxi

**Nome commerciale / Brandname:**

Spirobank Oxi; Smart One Oxi

**Classe di rischio / Risk class:**

II a

**Tipologia / Type:**

Z12150180 - Strumentazione per spirometria - accessori hardware / *Spirometry instruments - hardware accessories*

Kiwa Cermet Italia S.p.A.  
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**CERMET**

MOD P022A2\_MED\_MDR rev. 2

Presidente / President  
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Revisione /  
Revision

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2023-07-10

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Previous Expiry

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

### Identificazione dei Dispositivi / *Devices identification:*

**Nome / Name:**

Boccaglio in plastica / *Plastic mouthpiece*

**Modello / Model:**

Mouthpiece

**Nome commerciale / Brandname:**

Mouthpiece

**Classe di rischio / Risk class:**

II a

**Nome / Name:**

Turbina con boccaglio in carta monouso / *Disposable turbine with cardboard mouthpiece*

**Modello / Model:**

FlowMIR; Nuvoair

**Nome commerciale / Brandname:**

FlowMIR; Nuvoair

**Classe di rischio / Risk class:**

II a

**Nome / Name:**

Turbina riutilizzabile con boccaglio in plastica monouso / *Reusable turbine with single use plastic mouthpiece*

**Modello / Model:**

Single patient reusable turbine

**Nome commerciale / Brandname:**

Single patient reusable turbine

**Classe di rischio / Risk class:**

II a

CERTIFICATE

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Notified Body nr. 0476

**CERMET**

MOD P022A2\_MED\_MDR rev. 2

Presidente / President  
*Giampiero Belcredi*

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Reg. Number

MDR 00020-A

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Valid until

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Revisione /  
Revision

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Valid from

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Last change date

2023-07-10

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# CERTIFICATE

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 periodica.

*This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the aforementioned types of devices that are subject to periodic survey.*

L'allegato tecnico è parte integrante del presente Certificato

*The technical sheet is an integrating part of this Certificate.*

**Kiwa Cermet Italia S.p.A.**  
Società con socio unico, soggetta  
all'attività di direzione e coordinamento  
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[www.kiwa.it](http://www.kiwa.it)

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

**Presidente / President**

*Giampiero Belcredi*

Firmato digitalmente da: BELCREDI GIAMPIERO  
Data: 10/07/2023 16:03:16



**Storia del Certificato**  
*Certificate History*

Rev. Rev.	Data Date	Descrizione modifica Description of Change	Rapporto di valutazione <sup>(1)</sup> del Certificate History
0	16/02/2023	Certificazione iniziale <i>Initial certification</i>	Rapporto di audit del / <i>Audit report dated:</i> 10-11-12/01/2023  Analisi documentazione tecnica del / <i>Technical documentation analysis dated:</i> 14/11/2022; 12/01/2023; 13/01/2023  Valutazione dati clinici del / <i>Clinical data assessment dated:</i> 03/05/2022; 12/01/2023; 13/01/2023
1	10/07/2023	Modifica indirizzo sede legale e operativa / <i>Change of legal and operational headquarters address</i>	Rapporto di audit del / <i>Audit report dated:</i> 30/05/2023  Analisi documentazione tecnica del / <i>Technical documentation analysis dated:</i> 18/04/2023, 26/04/2023

<sup>(1)</sup> I rapporti di valutazione sono disponibili su richiesta / *Assessment reports are available upon request*

CERTIFICATE

**Kiwa Cermet Italia S.p.A.**  
Società con socio unico, soggetta  
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**Organismo Notificato n. 0476**  
*Notified Body nr. 0476*

**CERMET**

MOD P022A2\_MED\_MDR rev. 2

**Presidente / President**  
*Giampiero Belcredi*

Firmato digitalmente da: BELCREDI GIAMPIERO  
Data: 10/07/2023 16:03:54