DICHIARAZIONE DI CONFORMITA' CE
DECLARATION OF CONFORMITY CE

(Allegato II escluo par.4)
(annex II excluding par.4)

MIR - Medical International Research S.p.A. fabbricante del seguente dispositivo:
MIR - Medical International Research S.p.A. manufacturer of the following device:

Tipo *Type*	**Turbina monouso con boccaglio in carta** *Disposable turbine with cardboard mouthpiece*
Marca *Brandname*	**MIR - Medical International Research**
Nome Dispositivo *Device name*	**FlowMIR**
Classe di rischio *Risk Class*	**IIa**

dichiara che questo è conforme ai Requisiti Essenziali della Direttiva 93/42 sui Dispositivi Medici e successive modifiche, e al D.Lgs 46/97 e successive modifiche ed integrazioni.
La presente dichiarazione è basata sul Certificato CE n. MED 9826 emesso da Kiwa Cermet Italia s.p.a., Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO), Ente Notificato n.0476.
La presente dichiarazione viene emessa in conformità alla Direttiva 93/42 e sotto la sola responsabilità del fabbricante.
hereby declares that it complies with the Essential Requirements of directive 93/42/EEC concerning Medical Devices, and its amendments, and its transposition in the Member States.
This declaration is made on the basis of the CE Certificate n. MED 9826 issued by KIWA CERMET ITALIA s.p.a., Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO), Notified Body n. 0476.
This declaration is issued in compliance with Directive 93/42 and under the sole responsibility of the manufacturer.

Roma, 09.05.2022
Lugo, data
Place, date

Giovanni Carlino
Amministratore Delegato
Chief Executive Officer

MIR – Medical international Research S.p.A.
Cap. Soc.: Eur 120.000,00 i.v.
PI / CF / Reg. Imp.: 04564101006
Sede Legale (Head Office): Via del Maggiolino 125 – 00155 Roma

PEC: mirsrl-medicalinternationalresearch@pec.it
E.: mir@spirometry.com
T. +39 06 22 754 777 – F. +39 06 22 754 785
www.spirometry.com

CE ATITIKTIES DEKLARACIJA
(II priedas, išskyrus 4 dalį)

MIR – Medical International Research S.p.A. toliau nurodytų prietaisų gamintojas

Tipas: Vienkartinės turbinos su kartoniniais kandikliais

Prekės ženklas: MIR – Medical International Research

Prietaiso pavadinimas: FlowMIR

Rizikos klasė: IIa

šiuo dokumentu skelbia, kad prietaisai atitinka esminius direktyvos 93/42/EEB bei jos papildymų ir perkėlimo į Valstybes Nares dėl medicinos prietaisų reikalavimus.
Ši deklaracija parengta remiantis KIWA CERMET ITALIA s.p.a., Via Cadriano 23, 40057 – Granarolo dell`Emilia (BO), notifikuotosios įstaigos nr. 0476, CE sertifikatu nr. MED 9826.
Ši deklaracija išleista atsižvelgiant į 93/42 direktyvą ir yra gamintojo atsakomybėje.

Roma, 2022-09-05
Vieta, data

/parašas/
Giovanni Carlino
Direktorius

Išversta teisingai pagal mano žinias ir įsitikinimus. Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.
Aš esu užtikrintas, kad lietuvių kalbos vertimas atitinka originalų dokumentą.

Vaidas Vilmantas (MB „Beikeris“, įm .k. 304539005)

MIR – Medical International Research S.p.A.
Įstatinis kapitalas: 120.000,00 EUR
Įmonės kodas: 04564101006
Pagrindinis biuras: Via del Maggiolino 125 – 00155 Roma

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El. paštas: mir@spirometry.com
T: +39 06 22 754 777 – F: +390 06 22 754 785
www.spirometry.com

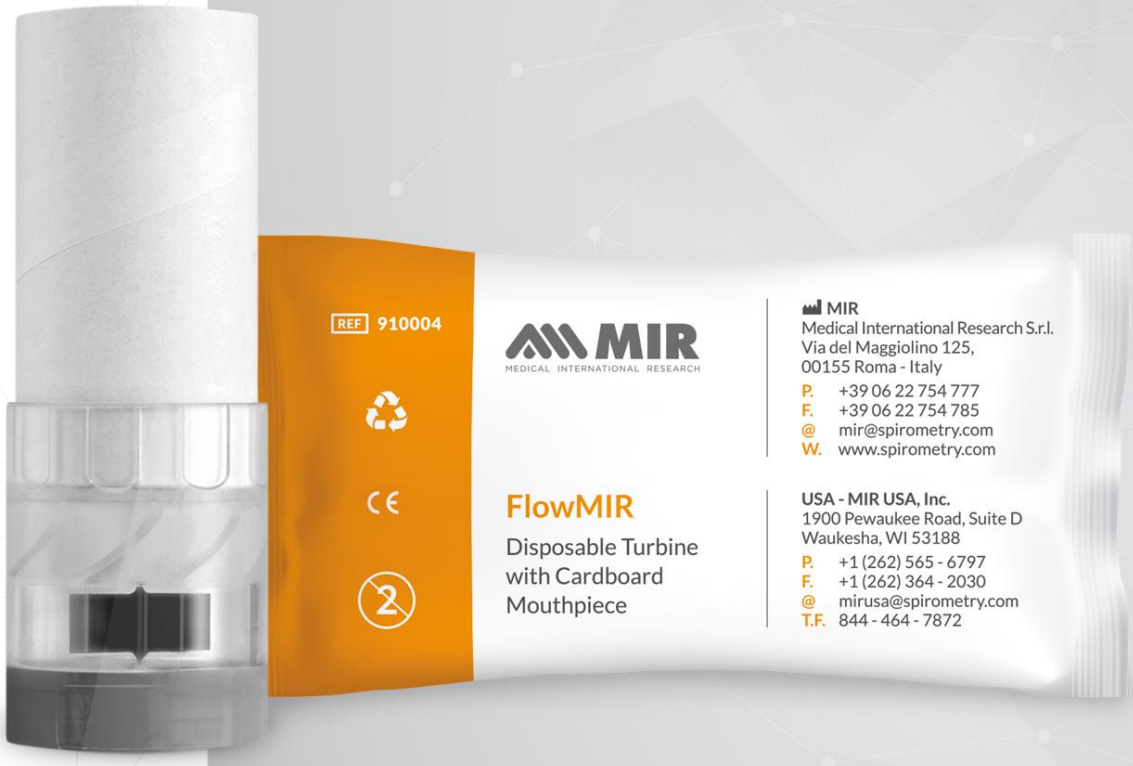
PATENTED

flowMIR™

Disposable Turbine Flowmeter, with cardboard mouthpiece

Vienkartinė turbina su kandikliu

The original and Patented disposable sensor, with turbine technology



MIR
MEDICAL INTERNATIONAL RESEARCH

www.spirometry.com

MAIN features

ACCURATE

Compliant with **ATS/ERS** accredited Spirometry Guidelines, including 2019 update with accuracy 2,5%

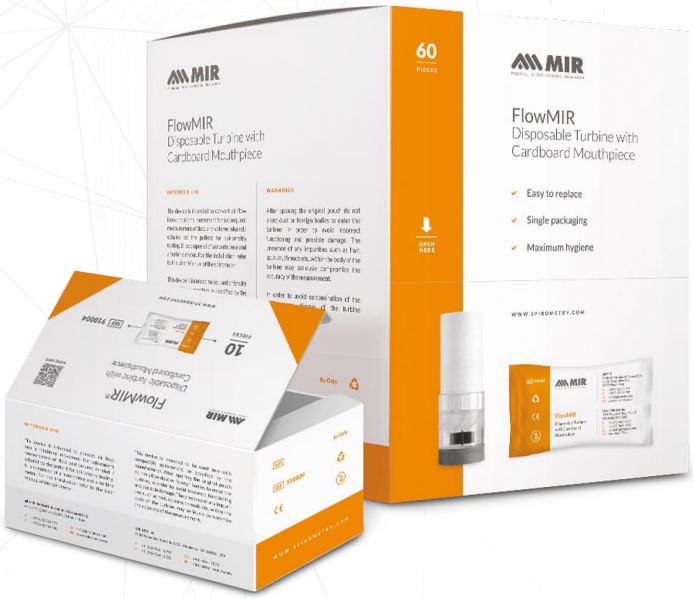
PORTABLE

Not affected by air pressure, humidity, temperature and viscosity. No need for a weather station.

Factory calibrated, no need for daily calibration check.

CLEAN

Physically isolated from inspiration and expiration flows. **Reduce cross-contamination risk**



DISTINCTIVE features

COMFORTABLE PACKAGING

Available in a 60 pcs or 10 pcs carton box. Easy to store. Easy to carry. **No expiration date.**

INDIVIDUALLY WRAPPED

Each turbine is individually sealed into an easy-to-open plastic bag.

CALIBRATION FREE

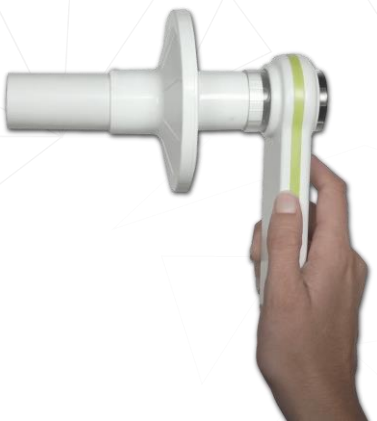
Factory calibrated, **no need for calibration** equipment and calibration procedure

DISINFECTION FREE

Hygienically sealed**, no need for cleaning** equipment and maintenance procedures

Also AVAILABLE

- Without cardboard mouthpiece (code 910001.).
- Compatible with disposable Anti-Viral filters (code 910302).



Sensor Flowmeter **OVERVIEW**

	TURBINE	Pneumotach	Ultrasonic
Affected by air pressure, humidity, temperature and viscosity	No	Yes	Yes
Affected by water condensation in expiration	No	Yes	No
Risk of "measurement drift" of the original signal	NONE (Infrared Sensor)	HIGH (Transducer + Filter)	VERY HIGH (Transducer + Control + Filter)
Complete physical isolation of the sensor from inspiration and expiration	YES	NO	NO
Calibration Required	NO	YES	YES

PLAY VIDEO

VISIT WEBSITE

TECHNICAL Datasheet Rev1

Product Code 910004

Dimension

External diameter	∅ 33.3 mm
Internal diameter	∅ 30.5 mm
Length	41.5 mm
Thickness	2 mm
weight	20.29 g
Mouthpiece	Ø 30 mm (1.18 inches)

Material

Transparent part	LEXAN 121R (policarbonate)
Deflector	LEXAN 121R (policarbonate)
Blade	HOSTAFORM C52021
Mouthpiece	pure cellulose or paper

Packaging

Packaging type	clean, not sterile
Pieces per box	10/60 pieces
Pieces per pallet	4800(480 boxes)/ 4200 pieces (70 boxes)
Phthalates	free
latex	free

Certificates & Registration

CE class	IIa
CE certificate	MED 9826
CND code	Z12150180
GMDN code	46906