MEDIKRO

MANUFACTURER'S DECLARATION

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and/or
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Medikro Oy
Manufacturer address and contact details	Pioneerinkatu 3, 70800 Kuopio, Finland
Single Registration Number (SRN)	FI-MF-000011841
Notified body	Eurofins Electric & Electronics Finland Oy
Notified body number	0537
EC Certificate number	C-01-1056-690-19
Expiry date of EC Certificate	27th May 2024
End date of extended validity/transition period	31st December 2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed Directive Certificate (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and/or
- the listed device(s) in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

Directive Certificate(s) as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.
- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- A Quality Management System (QMS) in accordance with Article 10(9) MDR is in place.
- Device(s) as listed in the attached schedule
  - The device(s) continue to comply with the AIMDD or MDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer: Tuukka Elo

Full Company Name:	Medikro Oy
Location & Date:	Kuopio, 2024-05-22
Signature, Print Name, Title	Tuukka Eloranta
Contact Details (at least email)	medikro@medikro.com

Schedule of Devices

MEDIKRO

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period
M914 Medikro® Primo Spirometer	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M914-E Medikro® Primo OEM Spirometer	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M915 Medikro® Pro Spirometer	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M915-E Medikro® Pro OEM Spirometer	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M915-WA, Spirometry kit, ref 410027	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M915-WA2, Spirometry kit, ref 410857	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M920 Medikro® Duo Spirometer	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M920-E Medikro® OEM Spirometer	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M9831 Medikro® Spirometry Software	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M9242 SpiroSafe Disposable Flow Transducer - M9242-100 (QTY 100) - M9242-SP-90 (QTY 90)	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M9242-B SpiroSafe Disposable Flow Transducer - M9242-B-100 (QTY 100) - M9242-B-SP-90 (QTY 90)	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M9242-WA Disposable Flow Transducer - M9242-WA-25 (QTY 25), ref 703418 - M9242-WA-100 (QTY 100), ref 703419	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M9256 SpiroSafe Disposable Flow Transducer, - M9256-100 (QTY 100) - M9256-SP-90 (QTY 90) - M9256-SP-50 (QTY 50)	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M9256-WA, Disposable Flow Transducers - M9256-WA-SP-4 (QTY 4), ref 725800 - M9256-WA-SP-25, (QTY 25) ref 720705 - M9256-WA-SP-100, (QTY 100) ref 720706	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M9256-A, Disposable Flow Transducer, - M9256-A-100 (QTY 100)	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028
M9256-MM, Disposable Flow Transducer, - M9256-MM-100 (QTY 100) - M9256-MM-SP-100 (QTY 100)	C-01-1056-690-19	27th May 2024	0537	0537	31st December 2028