

EC DECLARATION OF CONFORMITY

Issued by
Medikro Oy
Pioneerinkatu 3, 70800 Kuopio, Finland

Equipment Description:

This declaration of conformity is valid for the following product(s):

class IIa
M913 Medikro® Nano Spirometer
M913-E Medikro® Nano OEM Spirometer
M914 Medikro® Primo Spirometer
M914-E Medikro® Primo OEM Spirometer
M915 Medikro® Pro Spirometer
M915-E Medikro® Pro OEM Spirometer
M915-WA, ref 410027, Spirometry kit
M915-WA2, ref 410857, Spirometry kit (USB)
M920 Medikro® Duo Spirometer
M920-E Medikro® OEM Spirometer
M929 Medikro® SpiroStar USB Spirometer
M929-E Medikro® USB OEM Spirometer
M929-WA, ref 703554, Spirometer kit (USB)
M9831 Medikro® Spirometry Software
M9228 SpiroSafe Disposable Flow Transducer, M9228-100 (QTY 100)
M9242 SpiroSafe Disposable Flow Transducer M9242-100 (QTY 100)
M9242 SpiroSafe Disposable Flow Transducer M9242-SP-90 (QTY 90)
M9242-B SpiroSafe Disposable Flow Transducer M9242-B-100 (QTY 100)
M9242-B SpiroSafe Disposable Flow Transducer M9242-B-SP-90 (QTY 90)
M9242-WA, ref 703417, Disposable Flow Transducers (QTY 4)
M9242-WA, ref 703418, Disposable Flow Transducers (QTY 25)
M9242-WA, ref 703419, Disposable Flow Transducers (QTY 100)
M9256 SpiroSafe Disposable Flow Transducer, M9256-100 (QTY 100)
M9256 SpiroSafe Disposable Flow Transducer, M9256-SP-90 (QTY 90)
M9256-WA, ref 725800, Disposable Flow Transducers (QTY 4)
M9256-WA, ref 720705, Disposable Flow Transducers (QTY 25)
M9256-WA, ref 720706, Disposable Flow Transducers (QTY 100)

class I accessories
M911 Medikro® Ambi
M911-E Medikro® Ambi OEM
M91175 Outlet Port Adapter Kit for Calibration Syringes
M91227 Grip, M91227-25 (QTY 25)
M91227-WA, ref 721473, Handle WA Model
M9227 Nose Clip, M9227-100 (QTY 100)
M9252 Pressure Tube for M9228 and SpiroStar
M9253 Pressure Tube for M9242 and SpiroStar
M9253-B Pressure Tube for M9242-B and SpiroStar
M9253-WA, ref 703415, Pressure Tube for M9242-WA and WA Spirometer
M9264 Pressure Tube for M9256 (Pro, Primo and Nano spirometers)
M9264-WA, ref 720707, Spirometer Pressure Tube
M9274 Pressure Tube with grip
M9274-WA, ref 410370, Spiro Pressure Tube, Handle, CPWS-5, Cp150
M9278 Multivolume kit for M9474
M9353-50 USB A Female to USB A Male Cable
M9353-50W USB A Female to USB A Male Cable
M9354-180W USB Cable Micro-B Plug to A Plug
M9354-WA-21W, ref 720708, USB Cable Micro-B Plug to A Plug
M9354-WA-180W, ref 722444, USB Cable Micro-B Plug to A Plug
M9356-180W USB-A male to USB-C male cable
M9474 Calibration Syringe, volume 3000 ml
M9474-B Calibration Syringe, volume 3000 ml, Bird Healthcare OEM Model
M9474-C Calibration Syringe, volume 3000 ml, Cortex OEM Model
M9474-D Calibration Syringe, volume 3000 ml, DYN'R OEM Model
M9477 Calibration Syringe, volume 1000 ml

CE Marking:

These products have been developed, produced and tested within quality management system according to ISO 13485:2016 and directive 93/42/EEC. The quality management system is certified by Eurofins Expert Services Ltd (previously known as VTT Expert Services), notified body number 0537.

Applicable Directives:

The above products meet the essential requirements of the following directive(s):

Directive 93/42/EEC as amended by Directive 2007/47/EC.

Used Standards:

Following standards are used to fulfil requirements:

ISO 13485:2016, Medical devices, QMS
EN ISO 10993-1, Biological evaluation of medical devices
EN ISO 10993-5, Tests for in vitro cytotoxicity
EN ISO 10993-10, Tests for irritation and skin sensitization
EN ISO 14971:2012, Risk management
EN ISO 23747:2015, Anaesthetic and respiratory equipment
EN ISO 26782:2009, Anaesthetic and respiratory equipment
EN 60601-1:2006/A1:2013, General safety requirements for medical products
EN 60601-1-2:2014, Electromagnetic compatibility
EN 60601-1-6:2010/A1:2015, Usability
EN 60601-1-9:2007/A1:2013, Environmentally Designed
EN 62304:2006/A1:2015, Software life-cycle processes
EN 62366:2008+A1, Usability

Medikro Starter Kits:

Medikro Starter Kits M973, M937+911, M974, M975, M983, M983+911, M984 and M985 are system packages which contain products which are listed under Class IIa and Class I. These Medikro spirometer system starter kits consist of different combinations of Medikro spirometer products.

Place and Date
Kuopio, 2018-10-31



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