

MEDIKRO

EC DECLARATION OF CONFORMITY

Issued by
Medikro Oy
Pioneerinkatu 3, 70800 Kuopio, Finland
FI-MF-000011841

Equipment Description:

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

class I accessories

Device Group Basic UDI-DI: 6420099M9489LX

M911 Medikro® Ambi

M911-E Medikro® Ambi OEM

Intended use: Medikro Ambi is an ambient condition measuring unit. The ambient conditions of the operating environment affect the results measured and calculated by the spirometer. It is an optional accessory which is used as a part of Medikro Spirometry System.

Device Group Basic UDI-DI: 6420099M9474LJ

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

M91130 Outlet Port Adapter Kit for M9474 and M9477 Calibration Syringes

M91175 Outlet Port Adapter Kit for OEM Calibration Syringes

Intended use: 3 liter (type M9474) calibration syringe for spirometer calibration and calibration checking.

Device Group Basic UDI-DI: 6420099M91227B4

M91227 Grip, M91227-25 (QTY 25)

M91227-WA, ref 721473, Handle WA Model

Intended use: A patient grip for holding the flow transducer. It is an optional accessory which is used as a part of Medikro Spirometry System.

Device Group Basic UDI-DI: 6420099M9253KY

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

Intended use: Pressure tube is used to transmit pressure signal (pressure change) from flow transducer to spirometer unit. It is an accessory which is used as a part of Medikro Spirometry System.

Device Group Basic UDI-DI: 6420099M9264L5

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

M9278-B Multivolume kit

Intended use: Pressure tube is used to transmit pressure signal (pressure change) from flow transducer to spirometer unit. It is an accessory which is used as a part of Medikro Spirometry System.

Device Group Basic UDI-DI: 6420099M9477LQ

M9477 Calibration Syringe, volume 1000 ml

Intended use: 1 liter (type M9477) calibration syringe for spirometer calibration and calibration checking.

CE Marking:

These products have been developed, produced and tested within quality management system according to ISO 13485:2016 and regulation (EU)2017/745. The quality management system is ISO 13485:2016 certified by Eurofins Expert Services Ltd.

Applicable Regulation:

The products listed meet the safety and performance requirements of the following regulation:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

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 14971:2019, Risk management

EN ISO 20417:2021, Information to be supplied by the manufacturer

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 62366-1:2015/A1:2020, Usability

Medikro Starter Kits:

Medikro Starter Kits M974, M975, 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, 2022-09-30



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