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
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
M920 Medikro® Duo Spirometer
M920-E Medikro® OEM Spirometer
M9831 Medikro® Spirometry Software
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)
M9256-A, Disposable Flow Transducer, M9256-A-100 (QTY 100)
M9256-MM, Disposable Flow Transducer, M9256-MM-100 (QTY 100)

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, 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 1041:2008, Information supplied by the manufacturer of medical devices
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 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, 2021-04-13

Tuukka Eloranta
Medikro Oy,
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