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:

class I

(Spirometry/pulmonary function analyser syringe GMDN-code: 17250)

Device Group Basic UDI-DI: 6420099M9474LJ
M9474 Medikro Calibration Syringe, volume 3000 ml,
(GTIN: (01) 06420099000387)
Intended use: 3 liter (type M9474) 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 Directives:

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

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

Applied Standards:

Following standards are used to fulfil requirements:

- EN ISO 13485:2016
- EN ISO 14971:2019
- EN ISO 15223-1:2012
- EN ISO 20417:2021
- EN ISO 26782:2009
- EN 62366-1:2015/A1:2020

Place and Date
Kuopio, 2022-10-24

Tuukka Eloranta
Managing Director, Medikro Oy