Certificate of Compliance

Certificate: 2617324 **Master Contract:** 254243

Project: 2717765 **Date Issued:** April 9, 2014

Issued to: **Medikro, Oy**

3 Pioneerinkatu
FI-70800 Kuopio,
Finland
Attention: Mikko Hintikka

The products listed below are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US or with adjacent indicator 'US' for US only or without either indicator for Canada only.

Ruo Xuan Lim

Issued by: Ruo Xuan Lim

PRODUCTS

CLASS 8780 81 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS - Certified to US Standards
CLASS 8780 01 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS 8750 01 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS 8750 81 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS - Certified to US Standards

Part A:

Component type spirometer, model Pro (M9488), Primo (M9492), and Nano (M9487), rated: 5Vdc externally powered through means of USB PC connection.

Part B:

Component type ambient condition measuring unit, model Ambi (M9489), rated: 5Vdc externally powered through means of USB PC connection.

1. Medical device protection against electric shock: Externally powered through means of PC

2. Applied Part protection against electric shock: Type B

3. Degree of protection against ingress of water or particulate matter: IP20

4. Method of Sterilization: None

5. Suitability for use in an Oxygen Rich Environment: Medical device not intended to be used in an Oxygen Rich Environment

6. Suitability to use Medical device in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide: Medical device not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

7. Mode of operation: Continuous

8. Environmental Conditions: Normal: 10-40°C, 15-90% RH, 700-1060hPa

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA C22.2 601.1-M90	Medical Electrical Equipment part 1: General requirements for Safety adopted IEC 601-1 2ed (90)
CAN/CSA C22.2 601.1S1-94	Supplement No 1-94 to CAN/CSA C22.2 601.1-M90
CAN/CSA C22.2 601.1B-98	Amendment 2 to CAN/CSA C22.2 601.1-M90
CAN/CSA-C22.2 No. 60601-1:08	Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance (Adopted IEC 60601-1:2005 + CORR.1)
CAN/CSA-C22.2 No. 60601-1:08 TC 2:2011 (Corrigendum 2)	Technical Corrigendum 2:2011 to CAN/CSA-C22.2 No. 60601-1:08 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 - CORR.2)

UL Standards:

UL 60601-1 (1st edition)	Medical Electrical Equipment part 1: General requirements for Safety

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005 (IEC 60601-1:2005, MOD)	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
ANSI/AAMI ES60601-1:2005 / C1:2009 (CORRIGENDUM 1)	

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	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Corrigendum 1

Subject to the following qualifications:

(1) Evaluated to CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 excluding (Not Evaluated) requirements for Electromagnetic compatibility (Clause 17), Usability (Clause 7.1.1 and 12.2), Biocompatibility (Clause 11.7)

(2) SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

(3) Interconnection of this medical device with other medical devices, medical used systems or non medical devices shall be evaluated to the requirements of Clause 16 in the end use application.

(4) Safety Risk Management: A risk management process complying with the requirements of standard ISO 14971 was inspected during the evaluation of this medical device and/or additional considerations were taken into account since the subject legacy medical device was evaluated to the previous edition of this standard. The risk management decisions affecting the testing requirements have been taken into consideration during the evaluation of this medical device. Changes/Updates in risk management documents during the lifecycle of this medical device that affect the safety of this medical device shall be communicated to the CSA Group as a condition for continued compliance.