Certificate of Compliance

Certificate: 70037370 **Master Contract:** 202382 (202382)

Project: 70169595 **Date Issued:** 2018-01-11

Issued to: **ndd Medizintechnik AG**
Technoparkstrasse 1
Zurich, 8005
SWITZERLAND
Attention: Malou Mathys

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.

Issued by: Stefan Hofmann
Stefan Hofmann

PRODUCTS

CLASS - C878001 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS
CLASS - C878081 - MEDICAL ELECTRICAL EQUIPMENT/SYSTEMS-Certified to US Standards

Medical Electrical Equipment, Lung Function Analyser, Model/Type: EasyOne Pro / EasyOne Pro LAB, cord-connected: appliance coupler, transportable, rated: 100-240Vac, 50-60Hz, 80VA

1. Medical device protection against electric shock: Class I
2. Applied Part protection against electric shock: Type BF
3. Degree of protection against ingress of water or particulate matter: IP20
4. Method of Sterilization: None
5. Medical device is not intended to be used in an Oxygen Rich Environment.
6. 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: 5-40°C, 15-95% RH, 700-1060hPa as specified by manufacturer

APPLICABLE REQUIREMENTS

CSA Standards:

CAN/CSA-C22.2 NO. 60601-1:14	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005 edition 3.0 + AMENDEMENT 1, 2012-07, MOD)
CAN/CSA-C22.2 NO. 60601-1-6:11	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (Adopted IEC 60601-1-6:2010, third edition, 2010-01)

ANSI/AAMI Standards:

ANSI/AAMI ES60601-1:2005/(R)2012, AND c1:2009 AND a2:2010(r)2012 (CONSOLIDATED TEXT)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+A1:2012, MOD).
IEC 60601-1-6:10	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
ANSI/AAMI/IEC 62366:2006	Medical devices – Application of usability engineering to medical devices

MARKINGS

The manufacturer is required to apply the following markings:

- Products shall be marked with the markings specified by the particular product standard.
- Products certified for Canada shall have all Caution and Warning markings in both English and French.

Additional bilingual markings not covered by the product standard(s) may be required by the Authorities Having Jurisdiction. It is the responsibility of the manufacturer to provide and apply these additional markings, where applicable, in accordance with the requirements of those authorities.

The products listed are eligible to bear the CSA Mark shown with adjacent indicators 'C' and 'US' for Canada and US (indicating that products have been manufactured to the requirements of both Canadian and U.S. Standards) or with adjacent indicator 'US' for US only or without either indicator for Canada only.

Nameplate adhesive label material approval information:

For adhesive label material information see List of critical components. Adhesive label material tested according to IEC 60601-1 3rd edition Clause 7.1.2: Legibility of markings and Clause 7.1.3: Durability of markings.

The products listed 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

On the Equipment Exterior:

Equipment is plainly marked in a permanent manner in a place where the details will be readily visible after installation with the following:

- The CSA applicable mark  with optional reference to Standard, CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1:2005 as per adopted IEC 60601-1:2005 3rd edition
- Manufacturer's identification: Name and/or CSA file number on the same label as the CSA Mark. The name and/or trademark should appear elsewhere on the equipment if only the file number is used on this label.
- Catalogue/Model/Type designation.
- Date of manufacture: Month and year of manufacture or date code. If a serial number is used instead of date of manufacture, a record of serial numbers shall be kept traceable to date of manufacture. (Not related to date of sale).
- Marking on the unit that indicates the manufacturing location if the equipment is manufactured at more than one factory location.
- Complete electrical ratings; in volts (V), hertz (Hz), and amperes (A), Volt-amperes (VA) or Watts (W) with the IEC 60417-5032 alternating current symbol adjacent to the marked AC voltage and dc current symbol IEC 60417-5031 marked adjacent to DC input rating for each model.
- The IEC 60417-5840/5333/5335 "Type BF" or IEC 60417-5841/5334/5336 "Type BF" symbol for degree of protection against electric shock.
- The IEC 417-5021 equi-potential symbol adjacent to the equi-potential earth terminal.
- On the power supply cord or on the equipment there is a tag or label indicating that "GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTACLE MARKED 'HOSPITAL ONLY' OR 'HOSPITAL GRADE' " or equivalent wording.
- The IEC 60417-5008 and 60417-5007 symbols (I and O) adjacent to the mains power switch indicating "ON and OFF" positions.

Supplement to Certificate of Compliance

Certificate: 70037370 **Master Contract:** 202382 (202382)

The products listed, including the latest revision described below, are eligible to be marked in accordance with the referenced Certificate.

Product Certification History

Project	Date	Description
70169595	2018-01-11	Update of CoC report 70037370 based on FIR Follow-up 263826171108 to correctly identify a component
70145733	2017-08-23	Update of cCSAus Certification and Report 70037370 to change Label material and change Software version name in report from 2.05 to 3.00
70037370	2016-06-14	Testing according to project standards including issuing of CB and CSA certification