Certificate of Compliance

Certificate: 70037351 **Master Contract:** 202382

Project: 70037351 **Date Issued:** 2016-06-01

Issued to: **ndd Medizintechnik AG**
Technoparkstrasse 1
8005 Zürich
SWITZERLAND
Attention: Mr. Erich Kleinhappl

The products listed below 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 US Standards) or with adjacent indicator 'US' for US only or without either indicator for Canada only

Issued by: Ulrike Hiegemann
Ulrike Hiegemann

PRODUCTS

CLASS 8780 01 - MEDICAL ELECTRICAL EQUIPMENT (Canadian adopted IEC 60601-1 3rd edition)
CLASS 8780 81 - MEDICAL ELECTRICAL EQUIPMENT (US Adopted IEC 60601-1 3rd edition)

Medical Electrical Equipment, Respiratory Gas and Flow Analyser, Model/Type: EasyOne Air, internally powered (battery operated), portable/hand-held

- External SMPSU for charging of internal power source: INPUT 100-240 V~, 50-60 Hz, 160-80 mA; Output: 5.0 Vdc, 1.4 A, class II
- Internal power source: Lithium polymer, 3.6 Vdc, 3.4 Ah

1. Medical device protection against electric shock: Class II (charger) /Internally powered (EasyOne Air)
2. Applied Part protection against electric shock: Type BF
3. Degree of protection against ingress of water or particulate matter: no classification (IPX0)
4. Method of Sterilization: None
5. Medical device 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: 0-40°C, 5-90% RH, 700-1060hPa as specified by manufacturer

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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

Subject to the following qualifications:

(1) The main supply cord set provided with the Medical Electrical Equipment or the Medical Electrical System must be a North American Certified power supply cord set as indicated in the CSA description report.

(2) 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), Biocompatibility (Clause 11.7)

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

(4) 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.

(5) 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. During the evaluation of this medical device, the risk management decisions affecting the test requirements have been taken into consideration. Changes/Updates in risk management documents that affect the safety of this medical device during its lifecycle shall be communicated to the CSA Group as a condition for continued certification.

Supplement to Certificate of Compliance

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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
70037351	2016-06-01	Original Certification