EC Declaration of Conformity

Manufacturer:	ndd Medizintechnik AG
Address:	Technoparkstrasse 1 CH-8005 Zürich, Switzerland

Herewith we declare our sole responsibility for the declaration of conformity.

We declare under our sole responsibility that the medical device:

Product name:	**EasyOne Pro** and **EasyOne Pro LAB**
Product designation:	**Respiratory Analysis System**
Product type:	**Lung Function Analyzer** including accessories
Model number:	**3000-1** and **3100-1**
Classified as:	Class IIa according to annex IX, rule10 of directive 93/42/EEC

meets all provisions of the directive 93/42/EEC which apply to it.

Applied standards: See Appendix 1

ndd Medizintechnik AG follows the procedure related to the EC declaration of conformity set out in Annex II of Directive 93/42/EEC which involves the intervention of the Notified Body:

TÜV SÜD Product Service GmbH, Notified Body 0123
Ridlerstrasse 65, 80339 Munich, Germany

Validity of the Declaration of Conformity corresponds to the validity of the EC Certificate G1 005204 0002 Rev. 00.
This declaration of conformity covers the products that have been released for production from Serial Number 551000 (EOP) and 651000 (EOPL) onward.

Andreas Senn, Director
Regulatory Affairs & Quality

Georg Harnoncourt, CEO

Zurich, 24 May 2019

ndd Medizintechnik AG
Technoparkstrasse 1
CH-8005 Zürich
Tel. +41 44 512 65 00

Appendix 1: List of Applied Standards

Standard	Title of standard
EN 60601-1: 2006/A1:2013	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment, Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility- Requirements and tests
EN 60601-1-6:2010	General Requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366:2008	Medical devices – Part 1: Application of usability engineering to medical devices (IEC 62366:2007/A1:2014)
EN 62304: 2006/A1:2015	Medical device software - Software life-cycle processes
EN ISO 14971:2012	Application of risk management to medical devices
EN ISO 26782: 2009/AC:2009	Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans
EN ISO 23747: 2009	Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
EN ISO 10993-1: 2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5:1999	Biological evaluation of medical devices; part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2009	Biological evaluation of medical devices - part 10: Tests for irritation and skin sensitization
ISO 10993-12:2007	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
EN ISO 10993-18:2009	Biological evaluation of medical devices; part 18: Chemical characterization of materials
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices
IEC 60068-2-64:2008	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance
EN 22248:1992	Packaging - Complete, filled transport packages - Vertical impact test by dropping
ISO 2206:1987	Packaging -- Complete, filled transport packages -- Identification of parts when testing
MEDDEV 2.7/1 rev.4	Evaluation of clinical data