

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 Air**
Product designation: **Spirometry System**
Product type: **Respiratory Gas and Flow Analyzer**
including accessories
Model number: **2500**
Classified as: Class IIa
according to annex IX, rule 10 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:

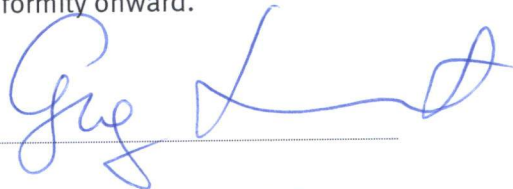
TÜV SÜD Product Service GmbH, Notified Body 0123
Ridlerstrasse 65, 80339 Munich, Germany

Validity of the Declaration of Conformity corresponds to the validity of the EC Certificate
G1 005204 0002 Rev.01.

This declaration of conformity covers the products that have been released for production from the date of issuance of this Declaration of Conformity onward.



Andreas Senn, Director
Quality & Regulatory Affairs



Georg Harnoncourt, CEO

Zurich, 13. May 2020

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/A1:2013 | General Requirements for basic safety and essential performance - Collateral standard: Usability |
| EN 60601-1-9:2008 | Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design |
| IEC 62366-1:2015 | Medical devices – Part 1: Application of usability engineering to medical devices |
| 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 23747:2015 | Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans |
| ISO 10993-1:2018 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| EN ISO 10993-5:2009 | Biological evaluation of medical devices; part 5: Tests for in vitro cytotoxicity |
| ISO 10993-10:2010 | Biological evaluation of medical devices - part 10: Tests for irritation and skin sensitization |
| EN ISO 10993-12:2012 | 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 + A1:2013 | 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 |

| Standard | Title of standard |
|--------------------|--|
| ISO 18562-1:2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process |
| ISO 18562-2:2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter |
| ISO 18562-3:2017 | Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs) |
| MEDDEV 2.7/1 rev.4 | Evaluation of clinical data |
| 2012/19/EU | DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE) |
| 2011/65/EU | DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment |