EU 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:	**Pulmonary Function Testing Devices**
Model number:	**3000-1** and **3100-1**
Classified as:	Class IIa according to annex IX of directive 93/42/EEC

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

Applied standards:	See Appendix 1
Authorised Representative:	**NDD Medizintechnik GmbH** Endersbacher Strasse 49 DE-71334 Waiblingen, Germany SRN: DE-AR-000032322

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 & Clinical Affairs

Michael Bencak
CEO

Zurich, 17. Aug. 2023

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

Standard	Title of standard
ISO 2206:1987	Packaging - Complete, filled transport packages - Identification of parts when testing
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 COUNCILof 4 July 2012on waste electrical and electronic equipment (WEEE)
2011/65/EU	DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCILof 8 June 2011on the restriction of the use of certain hazardous substances in electrical and electronic equipment

TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Deutschland

Product Service

Mehr Wert.
Mehr Vertrauen.

Andreas Senn
ndd Medizintechnik AG,
Technoparkstrasse 1,
CH-8005 Zürich,
SWITZERLAND

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
05204	713312800 Ashkan Ghassemloui	+49 1785199004 Ashkan.Ghassemloui@tuvsud.com	+49 89 50084-254	2024-02-09	1 von 3

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 005204 0005 Rev. 00

Reference: 713312800

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CH-MF-000015550

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

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If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 005204 0005 Rev. 00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-02-09

TÜV SÜD Product Service GmbH
Medical and Health Services

Ashkan Ghassemloui
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Franziska Eckert
Application Reviewer

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Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
EasyOne Pro LAB EasyOne Pro **764014219LungAnalyzer22**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate G1 005204 0002 Rev. 01; NB# 0123 Certificate #2; NB # or ☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-02-09	713312800	Initial issue