

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 of directive 93/42/EEC

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

Applied standards: EN ISO 14971:2012
EN 60601-1:2006/A1:2013
EN 60601-1-2:2015
EN 62366:2008
EN 62304:2006/A1:2015
EN ISO 26782:2009/AC:2009
EN ISO 23747:2009
EN ISO 10993-1:2009/AC:2010

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:

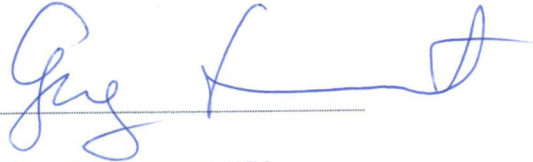
TÜV SÜD Product Service GmbH, Notified Body 0123
Ridlerstrasse 65, 80339 Munich, Germany

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 at
Variosystems AG from Serial Number 1120000 onward and at Zollner AG from Serial Number
1151000.



Andreas Senn, Director
Regulatory Affairs & Quality



Georg Harmoncourt, CEO

Zurich, 13 March 2019