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 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 from Serial Number 551000 (EOP) and 651000 (EOPL) onward.

Andreas Senn, Director
Regulatory Affairs & Quality

Georg Harnoncourt, CEO

Zurich, 13 March 2019