EC Declaration of Conformity

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

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 harmonized standards:	EN ISO 14971:2012 EN 60601-1: 2006/A1: 2013 EN 60601-1-2: 2015 EN 62366:2008 EN 62304:2006/AC:2008 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 2 of Directive 93/42/EEC which involves the intervention of the Notified Body:

SGS United Kingdom Ltd., Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK

Validity of the Declaration of Conformity corresponds to the validity of the EC Certificate CH00/51188.

G. Harnoncourt, CEO
Zurich, 13.03.2018