

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

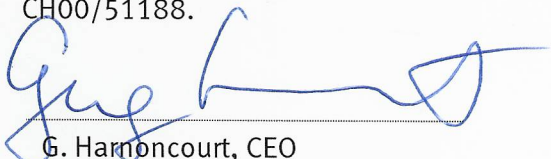
meets all provisions of the directive 93/42/EEC which apply to it.

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. Hamoncourt, CEO
Zurich, 13.03.2018