

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: **Easy on-PC**
Product designation: Spirometry System
Product type: Respiratory Gas and Flow Analyzer
including accessories
Model number: 2700-3
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
IEC 62304:2006/ A1:2015
EN ISO 26782:2009/AC:2009
EN ISO 23747:2009

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 DE00/51188.



G. Hannoncourt, CEO
Zurich, 09.08.2018