

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

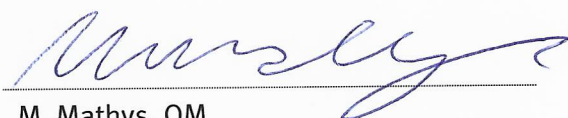
Product name: **EasyOne**
Product models: diagnostic, frontline
Product designation: Spirometry System
Product type: Respiratory Gas and Flow Analyzer
including accessories
Classified as: Class IIa
according to annex IX of directive 93/42/EEC

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

Applied harmonized standards: EN ISO 14971:2012
EN 60601-1: 2006
EN 60601-1-2: 2007
EN 62366:2008
EN 62304:2006/AC:2008
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 II 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

A handwritten signature in blue ink, appearing to read 'M. Mathys', is written over a horizontal dotted line.

M. Mathys, QM
Zurich, 03.Okt.2017

DoC_EasyOne_V27R