

EC Declaration of Conformity

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

declares under its sole responsibility, that the product

Product designation: **Spirometers and Accessories**
Product name: **EasyOne™ and Accessories:**

- **Spirettes**
- **Screen Connector**
- **EasyWare**

EasyOne has been classified as Class IIa and is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC.

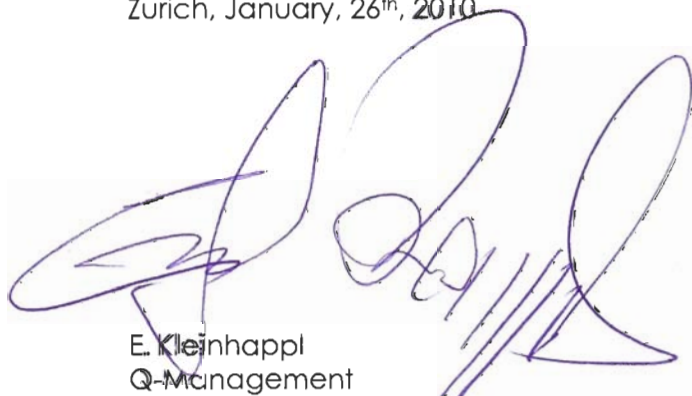
Accessories for EasyOne™ have been classified as Class I and meet all of the provisions of the Directive 93/42/EEC,

is in conformity with the following standards transposing harmonized standards:

EN 1041:1998
EN ISO 14971:2000 and A1 : 2003
EN 60601-1: 1990 and A1 :1993 and A2 : 1995
EN 60601-1-1: 2001
EN 60601-1-2: 2001
EN 60601-1-4: 1996 and A1: 1999

is subject to the procedure set out in ISO 9001:2008, ISO 13485:2003, and in Annex 2 of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd Systems & Services Certification 202B Worle Parkway, Weston-super-Mare, BS22 6WA UK

Zurich, January, 26th, 2010

A handwritten signature in blue ink, appearing to be 'E. Kleinhapfl', is written over a light blue rectangular background. The signature is stylized and cursive.

E. Kleinhapfl
Q-Management

EasyOne-Conformity-V19