

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd. Hungary, H-1033 Budapest, Szőlőkert u. 4/b

PRODUCT

Spirometer

MODEL NUMBER:

PDD-301/SH; PDD-301/SHM

SERIAL NUMBER

This statement of conformity is valid in connection with the passed device traveler page.

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex IX

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

CONFORMITY ASSESSMENT PROCEDURE

Annex V. of 93/42/EEC directive


STANDARDS APPLIED

EN 60601-1:2006	EN 980:2008
EN 60601-1-2:2007	EN 1041:2008
EN ISO 13485:2003/AC:2009	EN ISO14971:2009
ATS/ERS Standardisation of Spirometry: 2005	EN 60601-1-6:2007
EN ISO 23747:2009	EN 62304:2006
EN ISO 26782:2009	EN 62366:2008
	EN ISO 10993-1:2009

NOTIFIED BODY

SGS Hungaria Kft. Systems & Services Certification
1531 Pf. 25. Sirály u. 4. H-1124 Budapest

BUDAPEST, 12 JAN 2012/



PISTON Kft
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Tamás HANKÓ, Mr
Quality Assurance Manager