

EC DECLARATION OF CONFORMITY

MANUFACTURER

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

PRODUCT

Dose controlled drug nebuliser

MODEL NUMBER:

PDD-301/p

SERIAL NUMBER

This statement of conformity is valid in connection with the passed production traveller.

CLASSIFICATION

Class IIb
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 ISO 14971: 2009
EN 60601-1-2:2007	EN ISO 13485:2003/AC:2009
EN 60601-1-6:2007	EN 62304:2006
EN 980:2008	EN 62366:2008
EN 1041: 2008	EN ISO 10993-1:2009

NOTIFIED BODY

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

BUDAPEST, 28 FEB 2012/


.....
Tamás HANKÓ, Mr
Quality Assurance Manager

PISTON KFT
1033 Budapest Szőlőkert u 4/b
Adószám: 10465905-2-41