

EC DECLARATION OF CONFORMITY

MANUFACTURER

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

PRODUCT

Nasal probe for rhinomanometer

MODEL NUMBER:

PNP-12, PNP-14, PNP-16, different sizes

LOT NUMBER

This statement of conformity is valid in connection with the signed packaging record

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 980:2008
EN 1041:2008
EN ISO 13485:2003/AC:2009
EN ISO 14971:2007
EN ISO 10993-1:2009

NOTIFIED BODY

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

BUDAPEST, 22 DEC 2011/


PISTON Kft
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Adószám: 10465905-2-41
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Tamás HANKÓ, Mr.
Quality Assurance Manager