

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

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

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

STANDARDS APPLIED

EN 980:2003
EN 1041:1998
ISO 14971:2007

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Grauen Stein



EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197	Registration Nr:	HD 2111265 01
	Report Nr:	C 2192133 E 01

MAIN ACCESSORIES

Not specified

BUDAPEST, 25 AUG 2008/



Kornél NAGY, Mr
Quality Assurance Manager