

EC DECLARATION OF CONFORMITY

MANUFACTURER

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

PRODUCT

Diffusion capacity test

MODEL NUMBER

PDT-111D

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

STANDARDS APPLIED

EN 60601-1:2005
EN 60601-1-1:2001
EN 60601-1-2:2001
EN 60601-1-4:1996
EN 60601-1-6:2004
EN 980:2003
EN 1041:1998
ISO 14971:2000

NOTIFIED BODY

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


EC CERTIFICATES


ISO 13485:2003	Registration Nr:	SX 60009710 0001
	Report Nr:	02192133 004
CE 0197	Registration Nr:	HD 2111265 01
	Report Nr:	C 2192133 E 01

MAIN ACCESSORIES

PCS-3000	Calibration syringe
PBF-30	Bacterial filter
MPA-30	Mouth piece

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Kornél NAGY, Mr
Quality Assurance Manager


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