

## EC DECLARATION OF CONFORMITY

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**MANUFACTURER**

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

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**PRODUCT**

Whole-body plethysmograph

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**MODEL NUMBER**

PDT-111P

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**CLASSIFICATION**

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

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**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

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**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

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**NOTIFIED BODY**

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

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**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


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**MAIN ACCESSORIES**

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

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**BUDAPEST, 25 AUG 2008**

  
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Kornél NAGY, Mr  
Quality Assurance Manager

