

## EC DECLARATION OF CONFORMITY

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**MANUFACTURER**

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

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**PRODUCT**

Audiometer

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**MODEL NUMBER:**

**PDD-401**

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**SERIAL NUMBER**

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

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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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**CONFORMITY ASSESSMENT PROCEDURE**

Annex V. of 93/42/EEC directive

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**STANDARDS APPLIED**


EN 60601-1:2006	EN 1041:2008
EN 60601-1-2:2007	EN ISO14971:2009
EN ISO 13485:2003/AC:2009	EN 60601-1-6:2007
EN 60645-1:2001	EN 62304:2006
EN ISO 389-1:2000	EN 62366:2008
EN ISO 389-8:2004	EN ISO 10993-1:2009
EN 980:2008	

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**NOTIFIED BODY**

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

**BUDAPEST, 22 DEC 2011/**

  
1033 Budapest Szőlőkert u 4/b  
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**PISTON Kft**  
Tamás HANKÓ, Mr.  
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