

EC CERTIFICATE
Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

No. 5-815-500-1702

The **Directorate of Device Testing and Clinical Engineering (EMKI)**
certifies that the manufacturer:

Piston Kft.
Szőlőkert u. 4/b
1033 Budapest
Hungary

for the products / product categories:

**Audiometers, devices for pulmonary function test and connecting mouth piece,
and bacterial filters**

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex V.

Registry number of the related audit report: **42-2064-2017**

This certificate is valid until **2022-02-23** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by EMKI as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Budapest, 2017-02-24



Head of EMKI



EMKI 1660

The authenticity and validity of the certificate are verifiable at EMKI.

ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate No. 5-815-500-1702

The certificate is valid for the following products / models:

Audiometers, devices for pulmonary function test and connecting mouth piece, and bacterial filters

	Type	Class
Audiometer	PDD-401	IIa
Spirometer	PDD-301/s	IIa
Rhinomanometer	PDD-301/r	IIa
Ergospirometer	PRE-201	IIa
Mouth piece	MPA-30	IIa
Bacterial and viral filter	PBF-100	IIa

The detailed description of the products is kept by EMKI under No. 42-2064-2017.

Issue: 1

Date: 2017-02-24

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