EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-885-200-2008

The **NEOEMKI National Medical Device Conformity Assessment and Certification LLC.** certifies that the manufacturer:

Piston Kft.
Seat: **1023 Budapest, Szemlőhegy u. 13.**
Manufacturing site: **1033 Budapest, Szőlőkert u. 4/b**
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 II.

Registry number of the related audit report: **NE/1017/2020**

This certificate is valid until **2024-05-26** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

This certificate is valid only with the attachment.

Budapest, 2020-08-12

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI 2537

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

ATTACHMENT TO EC CERTIFICATE

Additional information for Certificate No. 5-885-200-2008

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
Whole-body Plethysmograph and Diffusion Capacity Test	PDT-111/pd	IIa
Diffusion Capacity Test	PDT-111/d	IIa
Spirometer	PDD-301/sh	IIa
Spirometer and Rhinomanometer	PDD-301/sr	IIa
Spirometer and Oscillometer	PDD-301/so	IIa
Ergospirometer	PRE-201	IIa
Mouth pieces	MPA-30, PMP-30	IIa
Bacterial and viral filter family	PBF-100-W-M PBF-100-G-M PBF-100-G-C PBF-100-B-M PBF-100-B-C	IIa

Issue: 1 Date: 2020-08-12 First issued: 2020-08-12

László Imre
Managing Director

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.

EMKI