

Melléklet/Annex


NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY
Department of Medical Devices
Case no.: NNGYK/GYSZ/7593-3/2024

Subject: Certificate for third countries

Consultant: Cintia Sólyom

FREE SALES CERTIFICATE

Pursuant to the Article 60 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter: MDR), on behalf of of the National Centre for Public Health and Pharmacy (hereinafter referred to as 'NCPHP'), I hereby

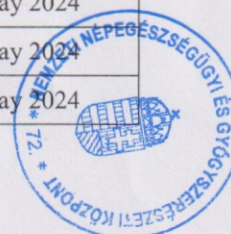
certify,

that Piston Kft. (H-1023 Budapest, Szemlőhegy u. 13. Hungary, tax number: 10465905-2-41, hereinafter referred as Client) is established in Hungary and that the medical device(s) described below bear(s) the CE marking pursuant to the Article 120 (3) of the MDR and may be freely marketed in the European Union.

Product name	Type	EC certificate nr.	EC certificate validity
Audiometer	PDD-401	5-885-200-2008	25 May 2024
Whole-body Plethysmograph and Diffusion Capacity Test	PDT-111/pd	5-885-200-2008	25 May 2024
Diffusion Capacity Test	PDT-111/d	5-885-200-2008	25 May 2024
Spirometer	PDD-301/sh	5-885-200-2008	25 May 2024
Spirometer and Rhinomanometer	PDD-301/sr	5-885-200-2008	25 May 2024
Spirometer and Oscillometer	PDD-301/so	5-885-200-2008	25 May 2024
Ergospirometer	PRE-201	5-885-200-2008	25 May 2024
Mouth pieces	MPA-30, PMP-30	5-885-200-2008	25 May 2024
Bacterial and viral filter family	PBF-100-W-M	5-885-200-2008	25 May 2024
	PBF-100-G-M	5-885-200-2008	25 May 2024
	PBF-100-G-C	5-885-200-2008	25 May 2024
	PBF-100-B-M	5-885-200-2008	25 May 2024
	PBF-100-B-C	5-885-200-2008	25 May 2024

NNGYK/GYSZ/7593-3/2024

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This certificate has been issued for export purposes, following a request by the Client. The free sales certificate has been prepared in Hungarian and English, of which the Hungarian text is authentic. In the event of inconsistency or discrepancy between the Hungarian version and the English versions of this publication, the Hungarian language version shall prevail.

This certificate is valid until 25 May 2024, provided that the information contained herein remains unchanged.

According to point d) of subparagraph (4) of Section 116 of the Administrative Procedure Act an appeal may not be lodged if no authority of second instance has been appointed. In this case clients may bring administrative action against definitive decisions pursuant to subparagraph (1) of Section 114 of the Administrative Procedure Act.

The issuance of the above certificate is based on Article 60 of the MDR and on Section 94 and Section 95 of Act CL of 2016 on General Public Administration Procedures (hereinafter referred to as Administrative Procedure Act). NCPHP is empowered to exercise official authority by Article 8, point 13 of Government Decree No. 333/2023 (20.VII.) on the National Centre for Public Health and Pharmacy.

Budapest, 19.02.2024.

Cecilia Müller MD.
chief medical officer
for and on behalf of

Gábor Szlobodnyik
Head of Department

