

NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY

Department of Medical Devices

Case no.: NNGYK/GYSZ/50077-3/2024 Subject: Free Sales Certificate Consultant: Katalin Szonja Gervald

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 Ltd. (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.

	Туре	Product name	CE cetificate number	EC certificate validity according to the Regulation EU 2023/607
1	PDD-401	Audiometer	5-885-200-2008	2028.12.31.
2	PDT-111/pd	Whole-body Plethysmograph and Diffusion Capacity Test	5-885-200-2008	2028.12.31.
3	PDT-111/d	Diffusion Capacity Test	5-885-200-2008	2028.12.31.
4	PDD-301/sh	Spirometer	5-885-200-2008	2028.12.31.
5	PDD-301/sr	Spirometer and Rhinomanometer	5-885-200-2008	2028.12.31.
6	PDD-301/so	Spirometer and Oscillometer	5-885-200-2008	2028.12.31.
7	PRE-201	Ergospirometer	5-885-200-2008	2028.12.31.
8	MPA-30, PMP-30	Mouth Pieces	5-885-200-2008	2028.12.31.

Székhely: 1097 Budapest, Albert Flórián út 2-6., Telephely: 1135 Budapest, Szabolcs utca 33., Tel.: +36 1 886 9300,

e-mail: fsc@nngyk.gov.hu

Hivatali kapu KRID azonosító: 346558928 (OGYEIEUGY)



	PBF-100-W-M PBF-100-G-M PBF-100-G-C PBF-100-B-M PBF-100-B-C	Bacterial and viral filter family	5-885-200-2008	2028.12.31.
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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.

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/MDD 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, 27.09.2024.

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

Norbert Kovács Head of Department