



Piston Kft.
Szemlőhegy utca 13.
1023 Budapest,
Hungary

Date: 27.05.2024

Confirmation Letter

To whom it may concern,

We hereby confirm that SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 on NANDO, has received a formal application from the following manufacturer, under the framework of (EU) 2017/745 and Regulation (EU) 2023/607.

Piston Kft.
Szemlőhegy utca 13.
1023 Budapest,
Hungary
SRN Number (if available): HU-MF-000017641

This letter confirms that the manufacturer's MDD certificate benefit from the extension period until 26 May 2024, provided the conditions set out in Article 120(3c), points (a) to (c), are fulfilled.

Received application is covering the following devices:

Class IIa devices:

Spirometer Devices, Basic-UDI 599956910PDD301SD

With accessories: mouth pieces, bacterial and viral filters, Piston XP PC client logging software.

Plethysmograph Devices, Basic-UDI: 599956910PDT111VN

Audiometer Devices, Basic-UDI: 599956910PDD401SJ

According to Regulation 2023/607 this MDD certificate can be extended till 31 December 2028 if a contract I signed in between SGS Belgium NV and Piston Kft. before 26 September 2024.

Please do not hesitate to contact us if you require any further information.

Yours sincerely,



On behalf of the Notified Body SGS Belgium NV 1639,

A handwritten signature in blue ink, appearing to be 'V. Siloret', with a long horizontal stroke extending to the right.

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