EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Performance Health International Ltd

Main Site: Nunn Brook Road, Huthwaite, Sutton in Ashfield, Nottinghamshire, NG17 2HU, United Kingdom

Product Category:

- Devices for muscle stimulation and biofeedback analysis,

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:
4130112942

Initial Certification Date:
22 April 2021

Certificate Valid from:
22 April 2021

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Mikael Hagelin
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

22 April 2021
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

MDD – Product List

T103-3-SE-MDD

Products included in the certificate no: 4130112942

Issued to: **Performance Health International Ltd**
Nunn Brook Road,
Huthwaite,
Sutton in Ashfield, Nottinghamshire, NG17 2HU, United Kingdom

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Devices for muscle stimulation and biofeedback analysis					
	91253731 Periform	IIa	MD1103	n/a	22 April 2021
	91253723 Periform	IIa	MD1103	n/a	22 April 2021
	91253640 Anuform	IIa	MD1103	n/a	22 April 2021
	91253632 Anuform	IIa	MD1103	n/a	22 April 2021
	91253715 NEEN Pericalm	IIa	MD1103	n/a	22 April 2021

Date of Issue: 22 April 2021

Intertek Semko AB
Notified Body MDD

Mikael Hagelin
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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