

CE DECLARATION OF CONFORMITY - EU

- 1) **Manufacturer: Performance Health International LTD**
Address: Nunn Brook Rd, Huthwaite, Sutton-in-Ashfield, Nottinghamshire, NG172HU,
United Kingdom
SRN: GB-MF-000003319

- 2) **European Authorized Representative:**
CEpartner4U BV,
Address: ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;
Printed on product labels as:
CEpartner4U,
ESDOORNLAAN 13, 3951 DB MAARN, THE NETHERLANDS.
www.cepartner4u.com
SRN: NL-AR-000000111

- 3) **Product(s):**

DEVICE FAMILY	DEVICE GROUP
MODALITIES	Women's Health

(see appendix); non-sterile and non-measuring devices

- 4) **The Product(s) Described Above Is In Conformity With:**

<u>Title</u>	<u>Document No.</u>
Medical Device Directive	93/42/EEC (LVFS 2003:11)

- 5) **Additional Information:**

Conformity assessment procedure for CE marking: Medical Device Directive Annex VII

Annex V (Periform and Anuform)

CE Certificate nr.: 4130112942 (LVFS 2003:11)

Initial Certification Date: 22 April 2021

Certificate Expiry Date: 21 May 2024

Notified Body.: Intertek Semko AB, Sweden. Torshamnsgatan 43, 164 40 Kista, Sweden

Notified Body nr.: 0413

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Nottinghamshire, UK; 2023-03-03

Signatory,

A handwritten signature in black ink, appearing to be 'D. Khan'.

VP, Regulatory and Quality

APPENDIX

<u>NO.</u>	<u>PART NO</u>	<u>EU DEVICE FAMILY</u>	<u>GROUP</u>	<u>EU SUB-GROUP CATEGORY</u>	<u>EU DEVICE DESCRIPTION</u>	<u>DEVICE NAME / PART NUMBER DESCRIPTION</u>	<u>RISK CLASS / RULE</u>
1	091253723	MODIALITIES	WOMEN'S HEALTH	PELVIC FLOOR EXERCISE DEVICES	PELVIC FLOOR EXERCISE DEVICES	NEEN PERIFORM + INTRA-VAGINAL PROBE	CLASS IIA / RULE 5
2	091253640	MODIALITIES	WOMEN'S HEALTH	PELVIC FLOOR EXERCISE DEVICES	PELVIC FLOOR EXERCISE DEVICES	NEEN ANUFORM INTRA-ANAL AND SMALL INTRA- VAGINAL PROBE	CLASS IIA / RULE 5
3	091253731	MODIALITIES	WOMEN'S HEALTH	PELVIC FLOOR EXERCISE DEVICES	PELVIC FLOOR EXERCISE DEVICES	NEEN PROBE PERIFORM PLUS FRENCH	CLASS IIA / RULE 5
4	091253632	MODIALITIES	WOMEN'S HEALTH	PELVIC FLOOR EXERCISE DEVICES	PELVIC FLOOR EXERCISE DEVICES	NEEN PROBE ANUFORM FRENCH	CLASS IIA / RULE 5