

UKCA DECLARATION OF CONFORMITY

Certificate No: PBIMTKS-UKCA-02

Identification of Company: POWERbreathe International Limited

Single Registration Number: N/A

General Product Name: POWERbreathe K/KH-Series (All Models)

Plant of Manufacture: 221 10F.-3, No.260, Sec. 2, New Taipei Blvd.,
Sanhong Dist., New Taipei City 241, Taiwan
(R.O.C.)

UK Representative: POWERbreathe International Ltd. Northfield Road,
Southam, Warwickshire. CV47 0FG

Intended Use: Training the inspiratory muscles

Sterile: No

Measuring Function: No

Directive Classification No: 1

GMDM Code: 31266

Harmonised Standards: EN 60601-1:2006
EN 60601-1-2:2007
EN 14971:2012
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 10993-10:2009
EN 1041:2008
EN 15223-1:20012

This declaration of conformity is issued under the sole responsibility of POWERbreathe International Limited. We hereby declare that the medical device(s) specified above meet the provisions of the United Kingdom Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), and follow the requirements of Directive 93/42/EEC as amended. This declaration is supported by the Quality System approval to ISO 13485 issued by LRQA. All supporting documentation is retained at the premises of the manufacturer.

Signed:**Date:** 24/03/21**Name:** Darren Hoe Yung Lam**Position:** Design Manager