EC DECLARATION OF CONFORMITY

Certificate No: PBIMTKS-CE-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., Sanchong Dist., New Taipei City 241, Taiwan (R.O.C.)
EC Representative	HaB GmbH, Porschestr. 4, D-21423 Winsen an der Luhe, Deutschland.
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 Regulation (EU) MDR 2017/745 for medical devices. 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