EC DECLARATION OF CONFORMITY

Certificate No: PBIMTP-CE-02.5

Identification of Company:	POWERbreathe International Limited
Single Registration Number:	N/A
General Product Name:	POWERbreathe Plus (for all variants see below)
Product Code and Description:	PB2000 POWERbreathe Medic Plus PB2001 POWERbreathe Plus Light PB2002 POWERbreathe Plus Medium PB2003 POWERbreathe Plus Heavy PB2004 POWERbreathe Plus Special Edition Black Light PB2005 POWERbreathe Plus Special Edition Black Medium PB2006 POWERbreathe Plus Special Edition Black Heavy PB2007 POWERbreathe Plus Special Edition Pink Light PB2008 POWERbreathe Plus Special Edition Pink Medium PB2009 POWERbreathe Plus Special Edition Pink Heavy
Plant of Manufacture:	POWERbreathe International Ltd. Northfield Road, Southam, Warwickshire. CV47 0FG
EC Representative:	HaB GmbH, Porschestr. 4, D-21423 Winsen an der Luhe, Deutschland.
Intended Use:	Training the inspiratory muscles
Sterile:	No
Measuring Function:	No
Device Risk Classification:	1
GMDN Code:	31266
Basic UDI-DI:	5060127400002NL

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: 01/12/22

Name: Darren Hoe Yung Lam

Position: Legal Representative and Design Manager for POWERbreathe International Limited