

# EC DECLARATION OF CONFORMITY

Certificate No: PBIMTP-CE-02

**Identification of Company:** POWERbreathe International Limited

**Single Registration Number:** N/A

**General Product Name:** POWERbreathe Plus (All Models)

**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

**Directive Classification No.** 1

**GMDM Code:** 31266

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:**

The stamp is circular with a red border. Inside the border, the text 'POWERbreathe International Ltd.' is written at the top, 'POWER breathe' is in the center, and 'Company Registration No. 7444642' is at the bottom.

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