

# EC DECLARATION OF CONFORMITY

Certificate No: PBRFTF-CE-02

**Identification of Company:** POWERbreathe International Limited

**Single Registration Number:** N/A

**General Product Name:** POWERbreathe TrySafe Filter

**Plant of Manufacture:** POWERbreathe International Ltd. Northfield Road,  
Southam, Warwickshire. CV47 0FG

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

**Intended Use:** Bacterial/viral filtration of respiratory air during  
inspiratory muscle training

**Sterile:** No

**Measuring Function:** No

**Directive Classification No.** 1

**GMDN Preferred Term Name** Breathing mouthpiece, single-use

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

