

This declaration of conformity is issued under the sole responsibility of the manufacturer.

EU DECLARATION OF CONFORMITYID: *INV-00000022*Name: *AF003 – Breathing Trainer*Model: *AF003*Version: *1.x*Manufacturer: *Airofit A/S**Rønnegade 1, 5th floor**Copenhagen Ø, 2100**Denmark**CVR: 37618772*GMDM Code: *11634: Exerciser, respiratory*Medical Device Directive amended 2007/47/EC: *Class I, rule 5*Electronical safety classification: *Type B*Software Classification: *Class A*Place of issue *Copenhagen*Date of issue *07-May-2021*

Among other, the following standards are met:

EN 60601-1-2:2015 *Medical electrical equipment :*IEC 60601-1-2:2014 *General requirements for basic safety and essential performance*IEC 62304:2006/A1:2015 *Medical device software: Software life-cycle processes*

The product listed above have been tested and found 'fit for intended use'.

The product technical documentation provides information on the **design, manufacture,** and **operation** of the product and contain the details necessary to demonstrate the product conforms to the applicable requirements.

The technical documentation proves the product meets the essential requirements and therefore justify and support this **EU declaration of conformity**.

This declaration of conformity is valid for products placed on the market within 2 years from the date of signature of this document. The technical documentation is stored for 10 years **from the date the product is placed on the market**

Christian Tullberg Poulsen

Chief Executive Officer

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TITLE

EU Declaration of Conformity

Version	Author	Date (DD-MMM-YYYY)	Comments
1.0	Kenn Milton	07-May-2021	This is the first approved version of this document.
2.0	Kenn Milton	See Approval Page for Last Signature	Updated the Manufacturer Address. Inserted 'Place of issue' and 'Date of issue'.

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