

# Declaration of Conformity

**AIROFIT**

Airofit A/S  
Titangade 11  
DK-2200 Copenhagen N  
Denmark

**We, the Manufacturer declare under our sole responsibility that the product**

Product name: Airofit Breathing Trainer  
Description: Exercising the respiratory musculature  
Product Number (P\N): AF002  
Additional Information: None

GMDN code and Term: 11634: Exerciser, respiratory  
Device Classification and Rule: Class I, rule 5 of annex IX  
Conformity Assessment Route: Annex II (full quality assurance)

The product is an invasive active therapeutically device.

The electrical safety classification according to IEC 60601-1 is Type B.  
The software classification according to IEC 62304 is Class A.


**to which this declaration relates is in conformity with the provisions of the  
Medical Device Directive, as amended to 2007/47/EC.**

The product listed above have been tested in a typical configuration as described in the  
Manufacturer's accompanying documentation.

Additionally, the products listed above have been designed, manufactured, tested, and found to be  
compatible with the devices and accessories described by the manufacturer in the devices  
accompanying documentation.

This declaration of conformity is valid for products placed on the market within 2 Years from the  
date of signature of this document.

Signature: \_\_\_\_\_

  
Christian Tullberg Poulsen  
CEO, Airofit A/S

Date of issue: \_\_\_\_\_

12/7 - 2019