

## Declaration of Conformity

We,

**ABMRC LLC**

860 Blue Gentian Road,  
Suite 200, Eagan,  
MN 55121, USA

Declare under our sole responsibility that the BiWaze Cough (BiWaze Airway Clearance System) product is produced by us.

**Brand Name:** BiWaze Cough

**Model Name:** BiWaze Cough

**Product Code:** NHJ- Noncontinuous Ventilator (IPPB) (USFDA)

**Product Class:** Class II (USFDA)

**Product Type:** Secretion Clearance Device

To which this declaration relates to the conformity with the following directives and standards:

- **EN 60601-1:** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **EN 60601-1-2:** Medical electrical equipment - Part1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- **EN 60601-1-6:** Medical electrical equipment - Part1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- **EN 60601-1-11:** Medical electrical equipment - Part1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- **EN ISO 10993-1:** Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing within a Risk Management Process
- **EN ISO 15223-1:** Medical Devices- Symbols to be used with medical device labels, labelling and information to be supplied- Part 1: General Requirements
- **EN ISO 14971:** Medical Devices- Application of Risk Management to Medical Devices
- **EN 62304:** Medical device software - Software life cycle processes
- **EN 62366-1:** Medical devices — Part1: Application of usability engineering to medical devices



- **IEEE C63.27:2017** – American National Standard for Evaluation of Wireless Coexistence

The authorized representative for the European Community (EC Rep) for this device is as below.

**Porta Medical UG**  
**Holstenstrasse 64a**  
**23701 Eutin**  
**Germany**

Signed for and on behalf of **ABMRC LLC, USA.**

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**Priyanka Paul**  
**QA/RA Manager**  
April 15, 2021

