## Declaration of Conformity

| **PRODUCT IDENTIFICATION** | | |
|---|---|---|
| **Product name** | | **Model/number** |
| Butterfly iQ Ultrasound System | | 850-20003 |
| **MANUFACTURER** | | |
| **Name of company** | **Address** | **Representative** |
| Butterfly Network, Inc, | 530 Old Whitfield St.<br>Guilford, CT 06437<br>USA | Kyle Burkhart |
| **AUTHORIZED REPRESENTATIVE** | | |
| **Name of company** | **Address** | **Telephone/email** |
| Emergo Europe | Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands | +31.70.345.8570 - phone<br>+31.70.346.7299 - fax<br>EmergoEurope@ul.com |

| **NOTIFIED BODY** | |
|---|---|
| **Notified Body and ID #** | **CE certificate number** |
| BSI Group The Netherlands B.V.<br>Say Building, John M. Keynesplein 9, 1066 EP<br>Amsterdam, The Netherlands<br>#2797 | 686786 |

| **CONFORMITY ASSESSMENT** | | | |
|---|---|---|---|
| **Device classification** | **Route to compliance** | **Standards applied** | |
| Class IIa<br>Rule 10 | Annex II of MDD 93/42/EEC Council Directive, excluding section 4 | IEC 60601-1 | Medical Electrical Equipment – Part 1. General requirements for basic safety and essential performance. |
| | | IEC 60601-1-2 | Medical Electrical Equipment – Part 1-2. General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances Requirements and tests |
| | | IEC 60601-2-37 | Medical Electrical Equipment – Part 2-37. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment |
| | | IEC 62359 | Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic field |
| | | IEC 62304 | Medical device software -- Software life cycle processes |
| | | ISO 14971 | Medical devices -- Application of risk management to medical devices |

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|---|---|---|---|
| | | ISO-10993-1 | Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing within a risk management process. |
| | | NEMA UD-2 | Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment |

**Butterfly Network, Inc.** declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices, Directive 93/42/EEC as transposed in the national laws of the Member States and manufactured in compliance with the Restriction of Hazardous Substances (RoHS), Directive 2011/65/EU.

**COMPANY REPRESENTATIVE:** Gioel Molinari

**TITLE:** President

**SIGNATURE:** 

**DATE:** 11/26/2019