BERRY® Shanghai Berry Electronic Tech Co., Ltd

# Declaration of Conformity

**Manufacturer**

Name：Shanghai Berry Electronic Tech Co., Ltd.

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Website: www.shberrymed.com

**European authorized Representative**

Name：Prolinx GmbH

Address：Brehmstr. 56, 40239, Duesseldorf, Germany

**Product: Pulse Oximeter**

**Type:BM1000C**

Classification (MDD, Annex Ⅸ): **Ⅱa, Rule 10**

We herewith declare under our sole responsibility that the abovementioned products meet transposition into national law, the provisions of the following EC Council Directives and Standards. The manufacturer is exclusively responsible for the Declaration of Conformity.

## DIRECTIVES

**General applicable directives:**

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC amended by 2007/47/EC concerning medical devices (MDD 93/42/EEC).

**Approach of application :** According to MDD 93/42/EEC evaluation procedures and certificate confirmation, the approach of application of product authentication is **Annex Ⅱ without section 4**.

**Notified Body:** TüV SüD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

**NB identification number: 0123**

**EC Certificate: G1 087056 0005 Rev.02**

**Expire date of the certificate: 2024-5-15**

**Date CE mark was affixed: 2019-05-16**

**Signature:** _____

**Name:** Xuezhi Yin

**Position:** General Manager

**Place:** Shanghai

Date: 2020-03-27