BERRY® Shanghai Berry Electronic Tech Co., Ltd

Declaration of Conformity

Manufacturer

Name: Shanghai Berry Electronic Tech Co., Ltd.

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Tel: + 86-21-5853 1958 Fax: +86-21-5853 0468

Website: www.shberrymed.com

European authorized Representative

Name: Prolinx GmbH

Address: Brehmstr. 56, 40239, Duesseldorf, Germany

Product: Pulse Oximeter

Type: BM1000 , BM1000A, BM1000B, BM1000C, BM1000D , BM1000E, BM2000A, BM2000B, BM2000C ,OSAsense S18, BM2000, BM2000D, BM2000E, BM2000F

Classification (MDD, Annex Ⅸ): **Ⅱb, 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: 2018-11-30

Signature: 尹学志

Name: Xuezhi Yin

Position: General Manager

Place: Shanghai

Date: 2019-3-20

Shanghai Berry Electronic Tech Co., Ltd 上海倍泰电子科技有限公司