BERRY® Shanghai Berry Electronic Tech Co., Ltd

Declaration of Conformity

Manufacturer

Name: Shanghai Berry Electronic Tech Co., Ltd.

Address: Unit 104, 1st Floor, 7th Building, No.1188 Lianhang Road, Minhang District, 201112 Shanghai, PEOPLE'S REPUBLIC OF CHINA

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

Add value.
Inspire trust.

TÜV SÜD Product Service GmbH· Ridlerstr. 65 · 80339 Munich · Germany

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TÜV SÜD Product Service GmbH
Confirmation Letter

CL 087056 0007 Rev. 00

Reference: 713337559

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000035103

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below:

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see: www.tuvsud.com/ps-cert?q=cert:CL 087056 0007 Rev. 00

In case of inquiries please contact: medical_devices@tuvsud.com

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-15

TÜV SÜD Product Service GmbH
Medical and Health Services

Mr. Shicheng Ni
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Mr. Konrad Fackler
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Pulse Oximeter **Models:** BM1000 BM1000B BM1000C BM1000D BM1000E **Basic UDI-DI:** 6924054301F1E7	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate No.: G1 087056 0005 Rev. 02 NB #0123
Pulse Oximeter **Models:** BM1000A BM2000A BM2000B BM2000C **Basic UDI-DI:** 6924054301HW18H	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate No.: G1 087056 0005 Rev. 02 NB #0123
Pulse Oximeter **Models:** OSAsense S18 BM2000 BM2000D BM2000E BM2000F **Basic UDI-DI:** 6924054301HW28K	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate No.: G1 087056 0005 Rev. 02 NB #0123

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SpO2 Sensor **Models:** BSA09001P BST09001S BSA09001B **Basic UDI-DI:** 69240543021RB	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate No.: G1 087056 0005 Rev. 02 NB #0123
Patient Monitor **Models:** PM6100 PM6100A PM6100B PM6100C **Basic UDI-DI:** 69240543031RE	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate No.: G1 087056 0005 Rev. 02 NB #0123

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-15	713337559	Initial issue