ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT 認證證書

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 087056 0005 Rev. 02

Manufacturer: **Shanghai Berry Electronic Tech Co., Ltd.**
Unit 104, 1st Floor, 7th Building
No. 1188 Lianhang Road
Minhang District
201112 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Prolinx GmbH
Brehmstr. 56, 40239 Duesseldorf, GERMANY

Product Category(ies): **Pulse Oximeter, Spo2 Sensor, Patient Monitor**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH19810EXT01

Valid from: 2019-05-16
Valid until: 2024-05-15

Date, 2019-03-08

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Digitally signed by Granaci Boris
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Reason: MoldSign Signature
Location: Moldova

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 13, 2015

Shanghai Berry Electronic Tech Co., Ltd
% Mr. Ray Wang
Official Correspondent
Beijing Believe Tech. Service Co., Ltd.
1-202, Build 3, Beijing New World, No.5 Chaoyang Road
Chaoyang District, Beijing, 100024
CHINA

Re: K142687
Trade/Device Name: Pulse Oximeter (BM1000A/ BM2000A)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: March 5, 2015
Received: March 12, 2015

Dear Mr. Wang,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit #2 Indications for Use

510(k) Number: K142687
Device Name: Pulse Oximeter (BM1000A/ BM2000A)

Indications for Use:

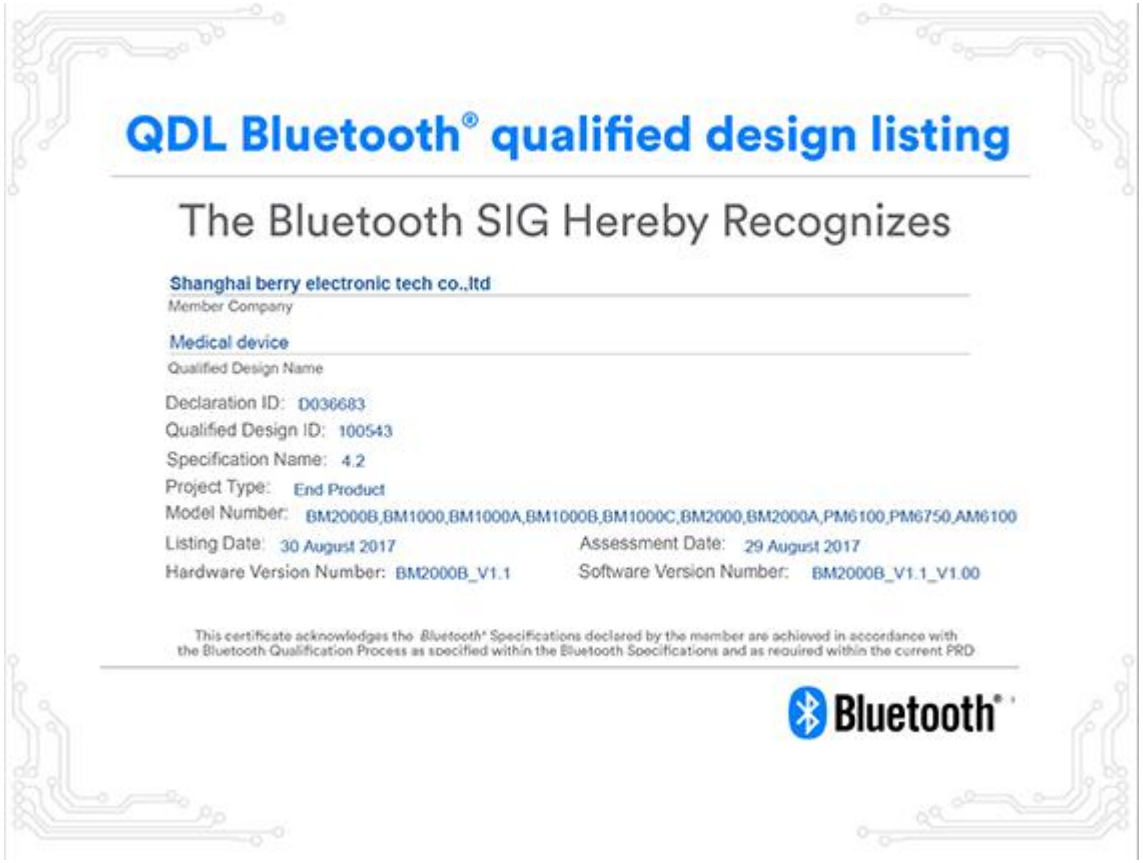
The pulse oximeter (BM1000A & BM2000A) is designed for spot checking of the pulse oxygen saturation and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously monitoring.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



QDL Bluetooth® qualified design listing

The Bluetooth SIG Hereby Recognizes

Shanghai berry electronic tech co.,ltd
Member Company

Medical device
Qualified Design Name

Declaration ID: D036683
Qualified Design ID: 100543
Specification Name: 4.2
Project Type: End Product
Model Number: BM2000B,BM1000,BM1000A,BM1000B,BM1000C,BM2000,BM2000A,PM6100,PM6750,AM6100
Listing Date: 30 August 2017
Assessment Date: 29 August 2017
Hardware Version Number: BM2000B_V1.1
Software Version Number: BM2000B_V1.1_V1.00

This certificate acknowledges the *Bluetooth*® Specifications declared by the member are achieved in accordance with the Bluetooth Qualification Process as specified within the Bluetooth Specifications and as required within the current PRD

Bluetooth®

CERTIFICATE OF CONFORMITY

CERTIFICATE

of Conformity

2011/65/EU Restriction of Hazardous Substance

Reference No.: LCS1501301261R

When tested as specified, the submitted sample complies with the requirements of Commission Decision of 21 July 2011 amending Directive 2011/65/EU.

Applicant	:	**Shanghai Berry Electronic Tech Co., Ltd.**
Address	:	**Unit C, 1stFloor, 7thBuilding, No.1188 Lianhang Road, Minhang District, Shanghai, China**
Trade Mark	:	**Berry**
Product	:	**Pulse Oximeter**
Model(s)	:	**BM1000A, BM2000A, BM2000B, BM1000B, BM1000C, BM1000D, BM1000E, BM2000G**

The test report is issued by the Company subject to its General Conditions of Service printed overleaf. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues defined therein. The results shown in this test report refer only to the sample(s) tested unless otherwise stated. This Test Report cannot be reproduced, except in full, without prior written permission of the Company.

Other relevant directives have to be observed.

RoHS

Manager

February 05, 2015

Shenzhen LCS Compliance Testing Laboratory Ltd.
1/F., Xingyuan Industrial Park, Tongda Road, Bao'an Avenue, Bao'an District, Shenzhen, Guangdong, China
Tel: (86)755-82591330 Fax: (86)755-82591332
Http://www.LCS-cert.com Email: webmaster@lcs -cert.com

TCB

GRANT OF EQUIPMENT AUTHORIZATION

TCB

Certification
Issued Under the Authority of the
Federal Communications Commission
By:

PHOENIX TESTLAB GmbH
Koenigswinkel 10
32825 Blomberg,
Germany

Date of Grant: 01/14/2014

Application Dated: 01/14/2014

Shanghai Berry Electronic Tech CO., Ltd
Suit C, 1st Floor, 7th Building,
N0.1188 Lianhang Road, Minhang District,
Shanghai, 201112
China

Attention: Jon Yin , Manager

NOT TRANSFERABLE

EQUIPMENT AUTHORIZATION is hereby issued to the named GRANTEE, and is VALID ONLY for the equipment identified hereon for use under the Commission's Rules and Regulations listed below.

FCC IDENTIFIER: 2AARYBM2000A
Name of Grantee: Shanghai Berry Electronic Tech CO., Ltd
Equipment Class: **Part 15 Spread Spectrum Transmitter**
Notes: **Pulse Oximeter**

Grant Notes	FCC Rule Parts	Frequency Range (MHZ)	Output Watts	Frequency Tolerance	Emission Designator
CC	15C	2402.0 - 2480.0	0.0009		

Output Power listed is peak conducted.

CC: This device is certified pursuant to two different Part 15 rules sections.

上海市电子证照库
zwdtcert.sh.gov.cn

医疗器械生产许可证

许可证编号 沪食药监械生产许20091645号

企业名称：上海贝瑞电子科技有限公司

生产地址：上海市闵行区联航路1188号7幢1层104单元

法定代表人：尹学志

生产范围：详见医疗器械生产产品登记表

企业负责人：尹学志

住　　所：上海市闵行区联航路1188号7幢1层104单元

发证部门：上海市药品监督管理局

有效期限：至　2026年　03月　14日

发证日期：　2021年　03月　15日

国家药品监督管理局制

统一社会信用代码

91310127547839537

证照编号：12000000202101190048

营业执照

（副 本）

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名　　称　上海贝瑞电子科技有限公司

类　　型　有限责任公司(自然人投资或控股)

法定代表人　尹学志

经营范围　许可项目：第二类医疗器械生产。（依法须经批准的项目，经相关部门批准后方可开展经营活动，具体经营项目以相关部门批准文件或许可证件为准）
一般项目：从事电子、计算机及通讯技术领域内的技术开发、技术转让、技术咨询、技术服务，电子电器、计算机、软件及辅助设备、汽摩配件、仪器仪表、电子设备、电力设备、机械配件、通讯设备及相关产品的销售，医用口罩的销售，日用口罩销售，自有设备租赁，传感器的研发、生产、销售，第二类医疗器械的销售，从事货物及技术的进出口业务。（除依法须经批准的项目外，凭营业执照依法自主开展经营活动）

注册资本　人民币531.5800万元整

成立日期　2003年09月25日

营业期限　2003年09月25日 至 2023年09月24日

住　　所　上海市闵行区联航路1188号7幢1层104单元

登记机关　上海市闵行区市场监督管理局

2021 年 01 月 19 日

仅用于验证使用

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

认证证书

证书号. Q5 087056 0006 Rev. 01

证书持有者： **上海贝瑞电子科技有限公司**
中华人民共和国上海市闵行区联航路1188号7幢1层104单元 201112

生产场地： **上海贝瑞电子科技有限公司**
中华人民共和国上海市闵行区联航路1188号7幢1层104单元 201112

认证标志：

tuv-sud.com/ps-cert

认证范围：
设计和开发，生产和分销：
脉搏血氧仪，血氧饱和度传感器，
病人监护仪
生产和分销：心电导联，血压袖带，
体温传感器

认证标准：
EN ISO 13485:2016
医疗器械 - 质量管理体系 - 用于法规的要求
(ISO 13485:2016)
DIN EN ISO 13485:2016

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。

报告号： SH2081001
生效期： 2020-06-29
有效期： 2023-05-15

发证日期， 2020-06-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

本证书是由具有法律效力的英文证书翻译而来

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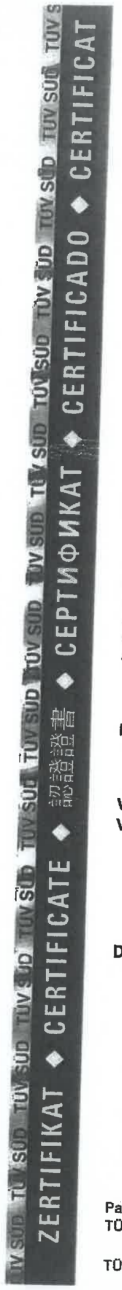

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Brehmstr. 56, 40239 Duesseldorf, GERMANY

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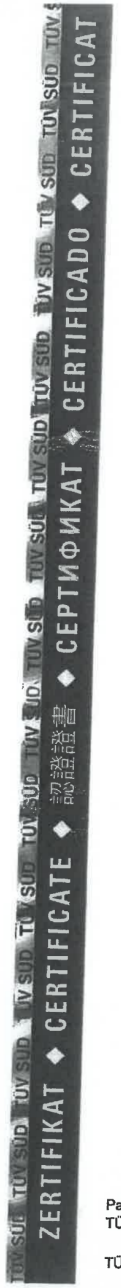

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