Dispositivo	1942562	S	BM1000D	PULSOSSIMETRO BM1000D	Z1203020408 - PULSOSSIMETRI	IIB - Classe IIb	07/04/2020		FABBRICANTE	SHANGHAI BERRY ELECTRONIC TECH CO., LTD.			CN
									MANDATARIO	PROLINX GMBH		815059178	DE

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

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

A4 / 07.17

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

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

Benannt durch/Designated by
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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

Facility(ies):

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

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

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Berry® Shangai Berry Electronic Tech Co.,Ltd

Dichiarazione di conformità

Produttore

Nome: Shangai Berry Electronic Tec Co., Ltd

Indirizzo: Unit 104, 1st Floor, 7th Building, No.1188 Lianhang Road, Minhang District, Shanghai, Cina 201112

Tel: TEL: +86-21-5853 1958 FAX: +86-21-5853 0420

Sito Internet: http://www.shberrymed.com/

Rappresentante Autorizzato dell'Unione Europea

Nome: Prolix Gmbh

Indirizzo: Brehmstr 56, 40239, Duesseldorf, Germania

Prodotto: Pulsossimetro

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

Classificazione (MDD, Annex IX): II b, regolamento 10

Con la presente dichiariamo sotto nostra responsabilità che i prodotti sopramenzionati sono conformi alle direttive nazionali trasposte ed alle direttive e standard seguite dall'Unione Europea. Il produttore è l'unico responsabile della suddetta dichiarazione di conformità.

DIRETTIVE

Direttive generali applicabili:

direttive sui dispositivi medicali: direttiva del consiglio 93/42 modificata dalla direttiva 2007/04 in materia di dispositivi medicali (MDD/93/42/EEC).

APPROCCIO APPLICATIVO: secondo la conferma di certificazione della procedura di validazione della direttiva MDD 93/42/EEC, l'approccio di applicazione dell'autenticazione del prodotto è quello espresso in Annex II senza considerare la sezione 4.

Ente notificato: TuV Sud Product Service GmbH, Ridlerstr. 65, 80339, Munchen, Germany

Numero indentificativo ente: 0123

Certificazione EC: G1 087056005 REV.02

Data di scadenza del certificato: 15/5/2024

Data di marcatura CE:30/11/2018

Firma:_____

Nome: Xuezhi Yin

Posizione: General Manager

Luogo: Shangai

Data: 20/3/2019

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

Product Service

Certificate

No. Q5 087056 0006 Rev. 00

Holder of Certificate:

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

Facility(ies):

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate:

**Design and Development,
Production and Distribution of Pulse Oximeter,
Spo2 Sensor, Patient Monitor,
Production and Distribution of ECG Cable,
Blood Pressure Cuff, Temperature Sensor**

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1881005

Valid from: 2018-11-30
Valid until: 2020-05-15

Date, 2018-11-30

Stefan Preiß

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

A4 / 07.17

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