深圳市亿米生命科技有限公司

Shenzhen Yimi Life Technology Co., Ltd.

Company Introduction

Shenzhen Yimi Life Technology Co.,Ltd. is a high-tech manufacturer dedicated to the research, development, manufacture and market of pulse oximeter.

Yimi passed the EN ISO 13485 quality system certification and CE certification by TUV SUD, and we got the FDA 510K in 2019.

Our pulse oximeter are being sold all over the world, especially hot sale in America, Europe, the Middle East and Africa, etc.

The average working experience of our team is more than 10 years. We have rich experience in ecg, blood oxygen, blood pressure, breathing and sleep monitoring, body temperature and other parameters, and we have our own intellectual property technology, aiming to provide a full range of services for domestic and global customers, including new product development, OEM/ODM, clinical validation and other services.

Address: 305, building A, Tengbo Industrial Park, Changshangjiang Street, Longbei Village, Pingshan District, 518118 Shenzhen, PEOPLE’S REPUBLIC OF CHINA.
Tell: 0755-86573112 Website: www.myspo2.com

深圳市亿米生命科技有限公司

Shenzhen Yimi Life Technology Co., Ltd.

Business License

营业执照

统一社会信用代码 91440300MA5ERHLH5K

名　　称　深圳市亿米生命科技有限公司

类　　型　有限责任公司

住　　所　深圳市坪山区坪山街道龙背村长上江横街腾博工业园A栋305

法定代表人　易尧

成立日期　2017年10月10日

重要提示

登记机关　深圳市市场监督管理局

2019 年 01 月 31 日

中华人民共和国国家工商行政管理总局监制

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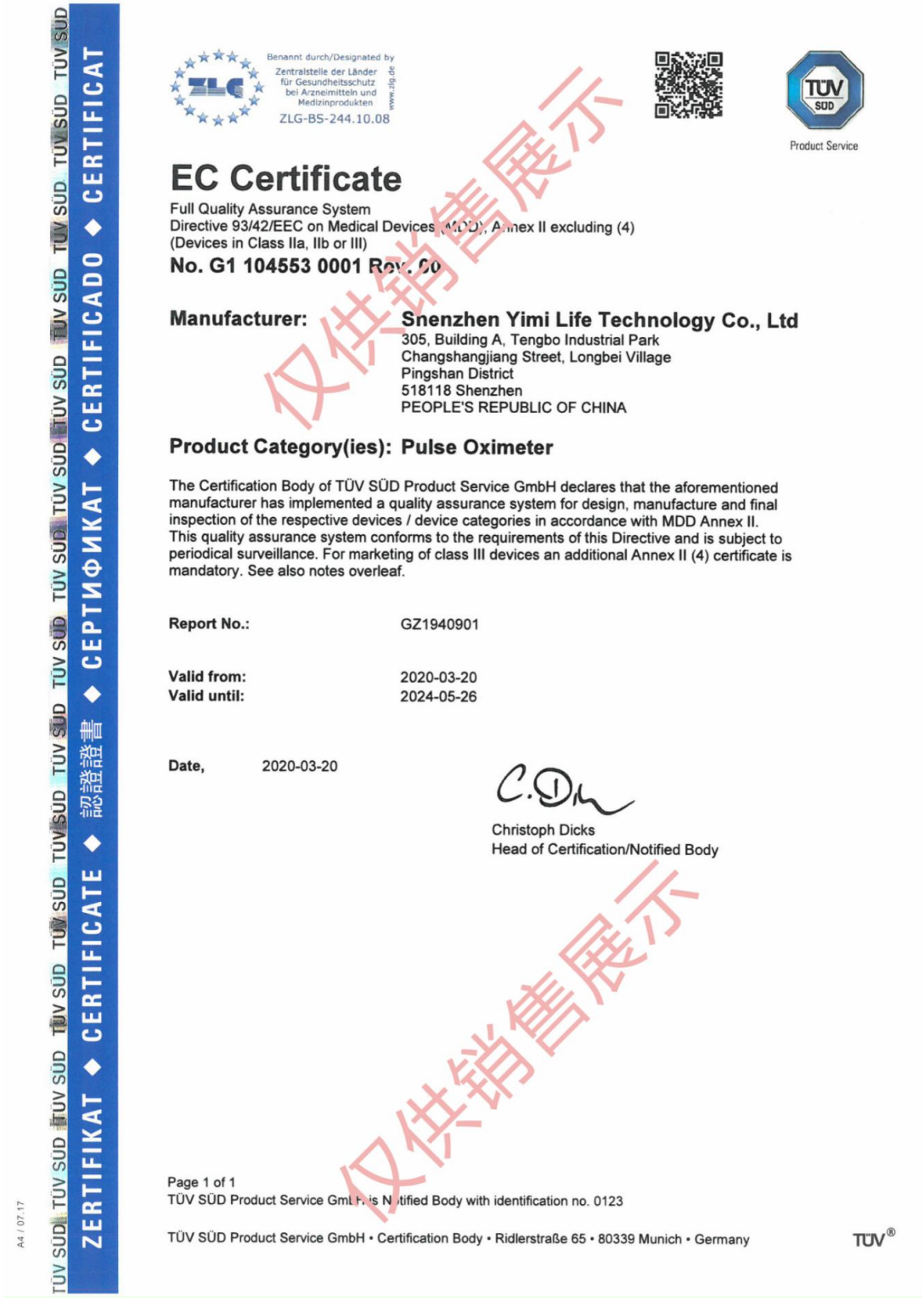
CE Certificate



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

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

TÜV SÜD 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 104553 0001 Rev. 00

Manufacturer: **Shenzhen Yimi Life Technology Co., Ltd**
305, Building A, Tengbo Industrial Park
Changshangjiang Street, Longbei Village
Pingshan District
518118 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Pulse Oximeter

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.: GZ1940901

Valid from: 2020-03-20
Valid until: 2024-05-26

Date, 2020-03-20

Christoph Dicks
Head of Certification/Notified Body

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

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ISO Certificate

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

TÜV SÜD Product Service

Certificate

No. Q5 104553 0002 Rev. 00

Holder of Certificate: **Shenzhen Yimi Life Technology Co., Ltd**
305, Building A, Tengbo Industrial Park
Changshangjiang Street, Longbei Village
Pingshan District
518118 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen Yimi Life Technology Co., Ltd
305, Building A, Tengbo Industrial Park, Changshangjiang Street, Longbei Village, Pingshan District, 518118 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Pulse Oximeter**

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.: GZ1940901

Valid from: 2020-03-20
Valid until: 2023-03-03

Date, 2020-03-20

Christoph Dicks
Head of Certification/Notified Body

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FDA 510K

U.S. FOOD & DRUG ADMINISTRATION

October 18, 2019

Shenzhen Yimi Life Technology Co.,Ltd.
Shande Peng
General Manager
305 Tengbo Industrial Park, Changshangjiang Street,
Longbei Village, Pingshan District
Shenzhen, 518118 CN

Re: K191430
Trade/Device Name: Pulse Oximeter, models YM101, YM201, YM301
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: September 10, 2019
Received: September 20, 2019

Dear Shande Peng:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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