

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

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

EUROPEAN REPRESENTATIVE: Share Info Consultant Service LLC Repräsentanzbüro
Heerder Lohweg 83, 40549 Düsseldorf, Germany

PRODUCT/MODEL: Pulse Oximeter/ YM101, YM102, YM103, YM201, YM203, YM301
The accessories are used together with the product. Not applicable

UMDNS/GMDN [name/code]: Oximeter / 12853

CLASSIFICATION: Class IIb, Rule 10 According To Annex IX of the MDD

CONFORMITY ASSESSMENT ROUTE: Annex II Excluding (4)

WE, SHENZHEN YIMI LIFE TECHNOLOGY CO. LTD., HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 INCLUDING AMENDMENTS BY DERECTIVE 2007/47/EC.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. SHENZHEN YIMI LIFE TECHNOLOGY CO. LTD IS RESPONSIBLE FOT THIS DECLARATION OF CONFORMITY

STANDARDS APPLIED:

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GmbH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER: 0123

(EC) CERTIFICATE(S): 2020-03-20 VALID UNTIL: 2024-05-26

START OF CE-MARKING: 2020-03-20

PLACE, DATE OF ISSUE: SHENZHEN, 2020-03-20

SIGNATURE: YIYAO
NAME YIYAO
GENERAL MANAGER



TUV SUD CERTIFICATE CERTIFICADO CERTIFICAT CERTIFICATE 證書 ZERTIFIKAT



Technik Güte Designated by
Zentralstelle der Länder
für Gesundheitschutz
bei Arzneimitteln und
Medizinprodukten
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 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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TUV SUD Product Service GmbH is a Notified Body with identification no. 0123

TUV SUD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TUV®



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DAkkS
 Deutsche
 Akkreditierungsstelle
 D-2M-11321-01-00



Certificate

No. Q5 104553 0002 Rev. 03

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:

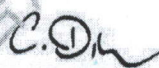


Scope of Certificate: Design and Development, Production and
 Distribution of Pulse Oximeter

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

