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:	YI YAO NAME YIYAO GENERAL MANAGER

Digitally signed by Moldoveanu Ruxanda
Date: 2022.02.21 10:33:08 EET
Reason: MoldSign Signature
Location: Moldova

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

Issued / Delivered by Zentralstelle der Länder für Gesundheitsschutz 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**
306, 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

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

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

TÜV®

IM.MOLDOVA mun. CHISINAU IDNO 1003600060828 I.M. «BECOR» S.R.L. PENTRU CONTRACTE SOCIETATEA CU RASPUNDERE LIMITATA

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

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

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

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