
Oximeter


FINGER CLIP
PULSE OXIMETER
P-01
Blood oxygen saturation was measured
Take the pulse
Measuring heart rate
P-01C
P-01B

Multi direction display

Rich monitoring functions

SpO_2

Pulse intensity
Column Zhuang form

PR

360 degrees

The screen rotates

Why use a oximeter to measure blood oxygen saturation?

OXYGEN SATURATION (SpO2), an important basic data of clinical medicine, is an important indicator of the state of OXYGEN in the body. The normal level of oxygen saturation in the blood (arteries) is not thought to be lower than 94%, and a lower level is considered inadequate. Low oxygen saturation can lead to dizziness, weakness and vomiting. In serious cases, it can be life-threatening.

Built in silicone
Double side antiskid

Built in silicone, anti slip, anti perspiration, no pressure on finger tip, blood flow is more smooth, measurement is more accurate, more comfortable.


31MM/3INCH
OXIMETR
BPM/PR
%SpO2
98
79
20.0
PI%
30MM/1.25INCH
57MM/2.3INCH


Oximeter

Packaging informatio

MADE OF
PURE SILICONE GEL

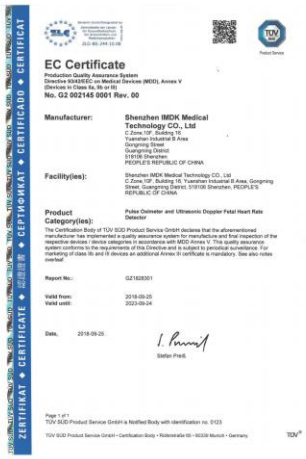
Not industrial grade silicone sheet
Not Silicone Oil cover on the surface.

CLOSED SILICONE
COVER DESIGN

Avoid touching components


OXIMETER
98
120
70
20.0

出口资质 Export qualification



EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 002145 0001 Rev. 00

Manufacturer: Shenzhen IMDK Medical Technology CO., Ltd
C Zone,10F, Building 16
Yuanshan Industrial B Area
Gongming Street
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen IMDK Medical Technology CO., Ltd
C Zone,10F, Building 16, Yuanshan Industrial B Area, Gongming Street, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Pulse Oximeter and Ultrasonic Doppler Fetal Heart Rate Detector

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

Report No.: G21828301

Valid from: 2018-09-25
Valid until: 2023-09-24

Date, 2018-09-25

Stefan Preiß

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

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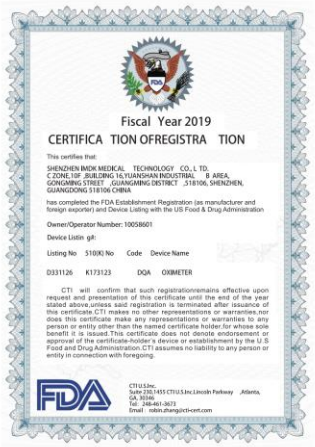

Fiscal Year 2019

CERTIFICA TION OFREGISTRA TION

This certifies that:

SHENZHEN IMDK MEDICAL TECHNOLOGY CO., L TD. C ZONE,10F ,BUILDING 16,YUANSHAN INDUSTRIAL B AREA, GONGMING STREET ,,GUANGMING DISTRICT ,518106, SHENZHEN, GUANGDONG 518106 CHINA

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration

Owner/Operator Number: 10058601

Device Listin g#:

Listing No	510(K) No	Code	Device Name
D331126	K173123	DQA	OXIMETER

CTI will confirm that such registrationremains effective upon request and presentation of this certificate until the end of the year stated above,unless said registration is terminated after issuance of this certificate.CTI makes no other representations or warranties,nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder,for whose sole benefit it is issued.This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S Food and Drug Administration.CTI assumes no liability to any person or entity in connection with foregoing.

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FDA

FDA Home[3] Medical Devices[4] Databases[5]

510(k) Premarket Notification

510(k)[7] | DeNovo[8] | Registration & Listing[9] | Adverse Events[10] | Recalls[11] | PMA[12] | HDE[13] | Classification[14] | Standards[15]

CFR Title 21[16] | Radiation-Emitting Products[17] | X-Ray Assembler[18] | Medsun Reports[19] | CLIA[20] | TPLC[21]

New Search — Back To Search Results

Device Classification Name	Oximeter[22]
510(K) Number	K173123
Device Name	Pulse Oximeter
Applicant	Shenzhen IMDK Medical Technology Co., Ltd. C Zone, 10F, Building 16, Yuanshan Industrial B Area Gongming Street Guangming District, Shenzhen, CN
Applicant Contact	Xia Yuan
Correspondent	Chonconn Medical Device Consulting Co., Ltd. 22A, Haijing Square No. 18, Taizi Road Nanshan District, Shenzhen, CN 518067
Correspondent Contact	Kevin Wang
Regulation Number	870.2700[23]
Classification Product Code	DQA[24]
Date Received	09/29/2017
Decision Date	08/13/2018
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Cardiovascular
510k Review Panel	Anesthesiology
Summary	Summary[25]
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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

Product Service

Certificate

No. Q6 002145 0002 Rev. 00

Holder of Certificate: **Shenzhen IMDK Medical Technology CO., Ltd**
C Zone,10F, Building 16
Yuanshan Industrial B Area
Gongming Street
Guangming District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen IMDK Medical Technology CO., Ltd
C Zone,10F, Building 16, Yuanshan Industrial B Area, Gongming Street, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Pulse Oximeter, Ultrasonic Doppler Fetal Heart Rate Detector**

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 (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: GZ1828301

Valid from: 2018-09-25
Valid until: 2021-09-24

Date, 2018-09-25

Stefan Preiß

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