MDD TEST REPORT

Report No.: SET2017-00303

Product: Pulse Oximeter

Model No. : C101H1, C101A2, C101A3, C101B1, C101B2

Brand Name: /

Applicant: Shenzhen IMDK Medical Technology Co., Ltd.

Issued by: CCIC Southern Electronic Product Testing (Shenzhen) Co., Ltd.

Lab Location: Electronic Testing Building, No. 43 Shahe Road, Xili Jiedao, Nanshan District, 518055 Shenzhen, Guangdong, China

Tel: 86 755 26627338 **Fax:** 86 755 26627238

Report No.: SET2017-00303

TEST REPORT
IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Compiled by (+ signature)	Macy. Yang	Macy Yang
Reviewed by (+ signature)	Bonnie. Nie	Bonnie. Nie
Approved by (+ signature)	Smart. Li	Smartli
Date of issue	2017.05.19	

Testing Laboratory	CCIC Southern Electronic Product Testing (Shenzhen) Co., Ltd.
Address	Electronic Testing Building, No. 43 Shahe Road, Xili Jiedao, Nanshan District, 518055 Shenzhen, Guangdong, China **Tel:** 86-755-26627338 **Fax:** 86-755-26627238
Applicant's name	Shenzhen IMDK Medical Technology Co., Ltd.
Address	C Zone, 10F, Building 16, Yuanshan Industrial B Area, Gongming Street, Guangming District, Shenzhen
Test specification:	
Standard	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) ANSI/AAMI ES60601-1:2005/ (R)2012 and A1:2012, C1:2009/ (R)2012 and A2:2010/(R)2012
Test procedure	Test report only
Non-standard test method	Not applicable
Test Report Form No.	IEC60601_1J
Test Report Form(s) Originator	UL(US)
Master TRF	2014-07
Test item description	Pulse Oximeter
Trade Mark	/
Manufacturer	Shenzhen IMDK Medical Technology Co., Ltd.
Address	C Zone, 10F, Building 16, Yuanshan Industrial B Area, Gongming Street, Guangming District, Shenzhen
Model/Type reference	C101H1, C101A2, C101A3, C101B1, C101B2
Ratings	DC 3V (2X1.5V AAA battery)

Copy of marking plate

ATTACHMENT FILE 1 photo of the DUT

Photo 1 [√] complete [ ] internal [ ] component [ ] PCB	

Photo 2 [√] complete [ ] internal [ ] component [ ] PCB	

Photo 3 [√] complete [ ] internal [ ] component [ ] PCB	

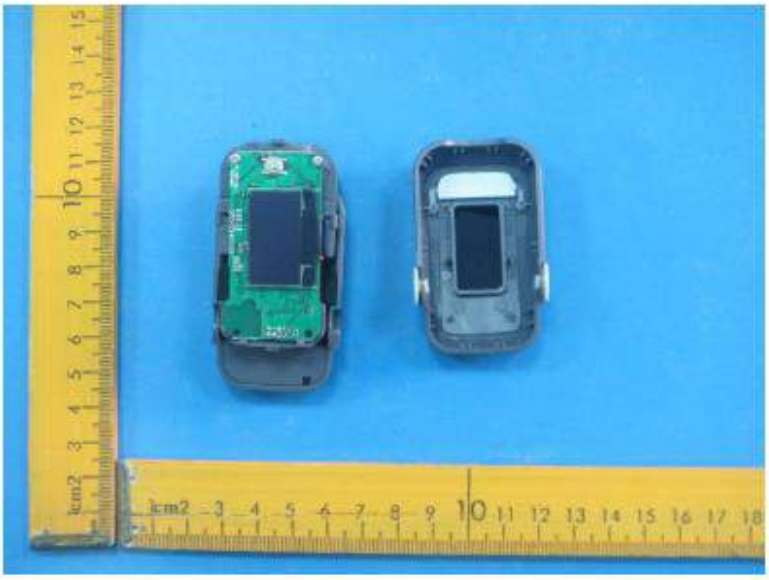
Photo 4 [ ] complete [√] internal [ ] component [ ] PCB	

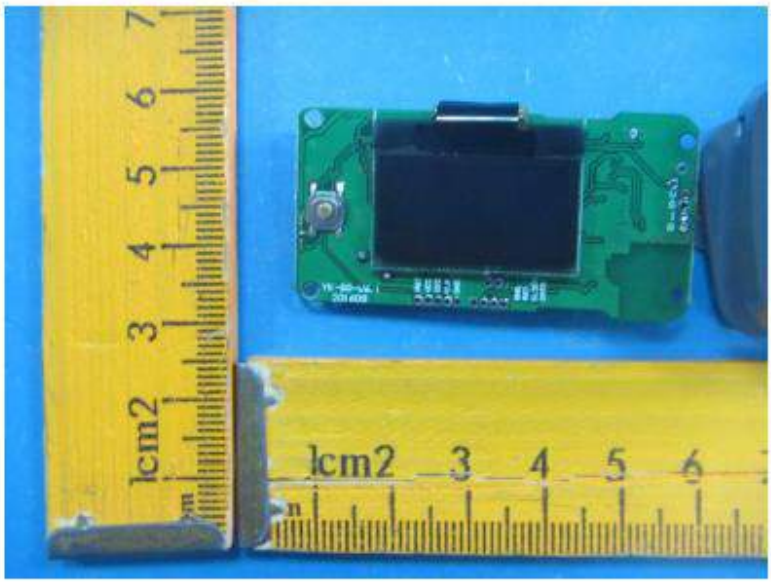
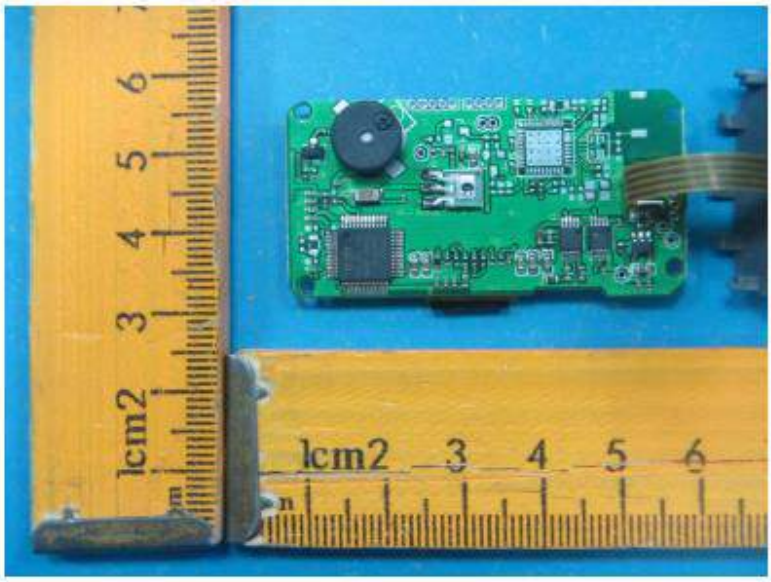
Photo 5 [ ] complete [√] internal [ ] component [ ] PCB	

Photo 6 [ ] complete [√] internal [ ] component [ ] PCB	

— End of Test Report —

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

Product Service

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 implemented a quality assurance system for manufacture 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 III certificate is mandatory. See also notes overleaf.

Report No.: GZ1828301

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

Date, 2018-09-25

I. Preuß

Stefan Preiß

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

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER: Shenzhen IMDK Medical Technology Co.,ltd
C Zone,10F,Building 16,Yuanshan Industrial B Area,Gongming Street,Guangming District,518106, Shenzhen.

MEDICAL DEVICE: Ultrasonic Doppler Fetal Heart Rate Detector, *YM-2T9*, *YM-2T8*

CLASSIFICATION - *ANNEX IX*: *CLASS IIA, RULE11*

CONFORMITY ASSESSMENT ROUTE: *ANNEX VII + V.3*

WE, THE MANUFACTURER, EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY, AND HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

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

IDENTIFICATION NUMBER: CE 0123

(EC) CERTIFICATE(S):

EC REP
EUROPEAN REPRESENTATIVE: MedNet GmbH, Borstrasse 10, 48163.Muenster, Germany.

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: Shenzhen,09/08/2018

SIGNATURE: XINYUN XIE 2018.8.9
POSITION: GENERAL MANAGER

MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC