PUL902

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

Stefan Preiß

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®

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

A4 / 07.17

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: *PULSE OXIMETER, C101H1/C101A2/C101A3/C101B1/ C101B2*

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 謝信云 2018.8.9.
POSITION: GENERAL MANAGER

MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.