

**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, RULE 11

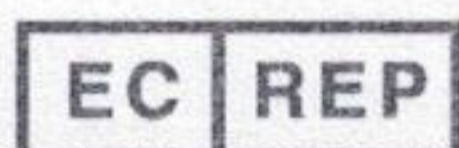
CONFORMITY ASSESSMENT ROUTE: ANNEX VII + V.3

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 MUNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): No. G2 002145 0001



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

START OF CE-MARKING:  26/04/2019

PLACE, DATE OF DECLARATION: Shenzhen, 26/04/2019

SIGNATURE:

POSITION:

XIE XINYUN

GENERAL MANAGER

谢信云 4/26-19

MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.