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,China.

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 MUNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): NO.G2 002145 0001 REV.00

EC REP

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

START OF CE-MARKING: 26/04/2019

PLACE, DATE OF DECLARATION: Shenzhen,22/4/2020

SIGNATURE: XIACHANGCHUN 夏长春
POSITION: GENERAL MANAGER

MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.