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

MANUFACTURER:
NAME:PROMISE TECHNOLOGY CO., LTD.
Add: 3/F, East-Asia Building, Jida Jiuzhou Avenue, Zhuhai, Guangdong, 519015 China

MEDICAL DEVICE: NAME: *Pulse Oximeter*
MODEL :PRO-F3, PRO-F4, PRO-F9, PRO-M130,PRO-M160,PRO-M170
CLASSIFICATION - *ANNEX IX*: *CLASS IIB, RULE10*

CONFORMITY ASSESSMENT ROUTE: *ANNEX II*

WE, THE MANUFACTURER, 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 M NCHEN, GERMANY

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): No. G1 16 07 91561 004

EC REP
EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg，Germany

START OF CE-MARKING:

PLACE, DATE OF DECLARATION: *ZHUHAI* *DATE:01-09-2019*

SIGNATURE Wang Xin Xin

NAME: WANG XINXIN
POSITION: GENERAL MANAGER