# 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 091561 0004 REV.01

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:04.12.2009*

SIGNATURE

*NAME: WANG XINXIN*
*POSITION: GENERAL MANAGER*

PROMISE TECHNOLOGY CO., LTD.