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, P.R.China

MEDICAL DEVICE: NAME: *Pulse Oximeter*
MODEL :PRO-F4, PRO-F8, PRO-F9, PRO-F9S, PRO-M110, PRO-M120, PRO-M130, PRO-M160, PRO-M170, PRO-PM350
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):

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:01-04-2018*

SIGNATURE wang xin xin

NAME: WANG XINXIN
POSITION: GENERAL MANAGER

Digitally signed by Potînga Stela
Date: 2019.12.04 13:11:26 EET
Reason: MoldSign Signature
Location: Moldova

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 07 91561 004

Manufacturer:

PROMISE TECHNOLOGY CO., LTD.
3/F, East-Asia Building
Jida Jiuzhou Avenue
519015 Zhuhai, Guangdong
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

B-Ultrasound Diagnostic System, Patient Monitor, Dynamic ECG Systems, Electrocardiograph, Pulse Oximeter, and Ambulatory Blood Pressure Monitor

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 7484032215

Valid from: 2016-09-19
Valid until: 2020-06-25

04052767033315

Date, 2016-09-19

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 07 91561 004

Facility(ies):

PROMISE TECHNOLOGY CO., LTD.
3/F, East-Asia Building, Jida Jiuzhou Avenue, 519015 Zhuhai,
Guangdong, PEOPLE'S REPUBLIC OF CHINA