

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE 2007/47/EEC) CONCERNING MEDICAL DEVICES

MANUFACTURER: Shenzhen Creative Industry Co., Ltd.
Floor 5, BLD 9, Baiwangxin High-Tech Industrial
Park, Songbai Road, Xili Street, Nanshan District,
518110 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: Fingertip Oximeter
Model: PC-60A/OXY-5, PC-60B, PC-60B1, PC-60B2,
PC-60B3, PC-60B5, PC-60C, OXY-6, PC-60C1,
PC-60C2, PC-60D, OXY-PED, PC-60D2, PC-60E,
PC-60NW/PC-60NW-1/PC-60N, POD-1/POD-2/
POD-3/POD-1W, PC-60F, PC-60FL

MEDICAL DEVICE: Handheld Pulse Oximeter
Model: PC-66A, PC-66B, PC-66V/OXY-100, SP-20
Accessories: Adult/Pediatric/Neonate sensor, IR Thermometer

CLASSIFICATION - ANNEX IX: Class IIa, Rule 10

CONFORMITY ASSESSMENT ROUTE: Annex II excluding(4)

WE, **Shenzhen Creative Industry Co., Ltd.**, 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 (AMENDED BY DIRECTIVE 2007/47/EEC) CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:

ISO 13485: 2016	EN/ISO 14971: 2012	EN 60601-1: 2006+A1: 2013
EN 60601-1-2: 2015	IEC 60601-1-6:2010+A1: 2013	IEC 60601-1-11: 2015
ISO 80601-2-61: 2011	ISO 15233-1: 2016	ISO 10993-5: 2009
ISO 10993-10: 2010	EN ISO 14155: 2011/AC:2011	EN1041: 2008+A1: 2013

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER 0123

(EC) CERTIFICATE(S): G1 049076 0016 Rev .02

EC REP

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

START OF CE-MARKING: OCT.15, 2010

PLACE, DATE OF DECLARATION: Floor 5, BLD 9, Baiwangxin High-Tech Industrial
Park, Songbai Road, Xili Street, Nanshan District,
518110 Shenzhen, PEOPLE'S REPUBLIC OF
CHINA,

SIGNATURE:

NAME:

FEB 05, 2020

POSITION: Management Representative