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: **Model:**	Fingertip Oximeter 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: **Model:**	Handheld Pulse Oximeter PC-66A, PC-66B, PC-66V/OXY-100, SP-20
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	IEC60601-1-6:2010+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) Eiffestraβe 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