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/Prince-100A/PC-60B/POD-1W/POD-1/ POD-2/POD-3/PC-60C/PC-60NW/PC-60N/ Prince-100N/PC-60B1/PC-60D/Prince-100D/ PC-60D2/Prince-100D2/PC-60E/PC-60F/PC-60FW/ Prince-100I
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:

EN/ISO 13485: 2016	EN/ISO 14971: 2012	IEC 60601-1: 2005+A1: 2012
IEC 60601-1-2: 2014	IEC 60601-1-6: 2010+A1:2013	IEC 60601-1-11: 2015
ISO 80601-2-61: 2017	EN 1041: 2008+A1: 2013	EN ISO 10993-5: 2009
EN ISO 10993-10: 2010	EN 14155: 2011	ISO 15223-1: 2016

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 M NCHEN, 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, Apr. 20, 2019
SIGNATURE:	**NAME:** Jan.10, 2020 **POSITION:** Management Representative