DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE2007/47/EC)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/ Prince-100I/PC-60F
CLASSIFICATION - ANNEX IX:	Class IIa, Rule 10
GMDN CODE:	45607
CONFORMITY ASSESSMENTROUTE:	Annex II excluding(4)

WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICESMEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 (AMENDED BY DIRECTIVE 2007/47/EC) 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:

ENISO 13485: 2016	ENISO 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 10993-1: 2009/AC:2010
EN ISO 10993-5: 2009	EN ISO 10993-10: 2013	EN 14155: 2011
EN ISO 15223-1: 2016		

NOTIFIED BODY:	TÜV SÜD Product Service GmbH . Ridlerstraβe 65.80339 Munich.Germany
IDENTIFICATION NUMBER	0123
(EC) CERTIFICATE(S):	G1 049076 0016 Rev .03

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: Shenzhen,Apr.8,2021

SIGNATURE:

NAME: Apr.8,2021

POSITION: Management Representative