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:	Vital Signs Monitor
Model:	PC-900, PC-900PRO, PC-900Plus PC-900S, PC-900SNT, PC-900SNET PC-900PRO SNET, PC-900Plus SNET
CLASSIFICATION - ANNEX IX:	Class IIb, Rule 10
GMDN CODE:	33586
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 60601-1-8: 2006+A1: 2012
IEC 80601-2-49: 2018	IEC 60601-2-27: 2011+ COR.1:2012	IEC80601-2-30: 2018
ISO 80601-2-61: 2017	ISO 80601-2-56: 2017	EN ISO 15223-1: 2016
IEC 62304: 2006+A1: 2015	EN 1041: 2008+A1: 2013	EN ISO 10993-1: 2009/AC:2010
EN ISO 10993-5: 2009	EN ISO 10993-10: 2013	

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