

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

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	EN 60601-1: 2006+AC: 2010
IEC 60601-1-2: 2014	EN 60601-1-6: 2010	IEC60601-1-8:2006
ISO 80601-2-61: 2011	ISO 80601-2-55: 2011	ISO 15233-1: 2016
EN 1041: 2008	EN/ISO 10993-1: 2009	EN/ ISO 10993-5: 2009
EN/ISO 10993-10: 2010	EN14155: 2011	

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