DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE2007/47/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: Patient Monitor

Model: PC-3000, UP-7000, PC-900S

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 DEVICESMEET 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	ENISO 14971: 2012	EN 60601-1: 2006+A1: 2013
EN 60601-1-2: 2015	EN 60601-1-6: 2010+A1: 2015	EN 60601-1-8:2007/A11:2017
IEC 80601-2-49: 2018	IEC 60601-2-27: 2011/Cor1:2012	IEC 80601-2-30: 2018
ISO 80601-2-61: 2017	ISO 80601-2-56: 2017	ISO 80601-2-55: 2018
IEC 62304: 2006+A1: 2015	ISO 10993-1: 2018	ISO 10993-5: 2009
ISO 10993-10: 2010	ENISO 15223-1: 2016	EN 1041: 2008+A1:2013

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

IDENTIFICATION NUMBER CE 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: April 6 2021
POSITION: Management Representative