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, PC-5000, UP-6000, UP-7000, UP-9000, Genius-15, Superview-12, K10, K12, K15
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 M NCHEN, GERMANY
IDENTIFICATION NUMBER	CE 23
(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, FEB 05,2020
SIGNATURE:	张翔
NAME:	
POSITION:	Management Representative