

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: 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 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:

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



(EC) CERTIFICATE(S): G1 049076 0016 Rev .02



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:

A handwritten signature in black ink, appearing to be the Chinese characters '张翔' (Zhang Xiang).

NAME: FEB 05, 2020

POSITION: Management Representative