

# 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

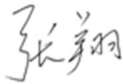
START OF CE-MARKING:

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:



NAME:FEB 05,2020

POSITION:Management Representative