

## DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE 2007/47/EC) 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:** Easy ECG Monitor

**MODEL:** PC-80B/Prince 180B/CARDIO-B/PC-80D

**CLASSIFICATION - ANNEX IX:** Class IIa, 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/EC) 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: 2019	EN 60601-1: 2006+A1: 2013+A2:2020
EN 60601-1-2: 2015+A1:2020	IEC 60601-1-11: 2010+A1:2020	EN 62304: 2006+A1: 2015
EN ISO 10993-1: 2020	EN 60601-1-6: 2010+A1:2015+A2:2020	EN 62366:2008+A1:2015+A2:2020
EN ISO 10993-5: 2009	EN 1041: 2008+A1: 2013	EN ISO 15223-1: 2021
EN ISO 10993-10: 2013		

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

**IDENTIFICATION NUMBER** 0123

**(EC) CERTIFICATE(S):** G1 049076 0016 Rev .03



**EUROPEAN REPRESENTATIVE:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, Germany

### START OF CE-MARKING:

**PLACE, DATE OF DECLARATION:** Shenzhen, Sept.30, 2021

**SIGNATURE:**  Sept.30, 2021

**NAME:** Zhang Xiang

**POSITION:** Management Representative