

# 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:** ECG Cable 15010012/15010008/15011920/15010020

**CLASSIFICATION - ANNEX IX:** Class I

**CONFORMITY ASSESSMENT ROUTE:** Annex VII

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 (INCLUDING DIRECTIVE 2007/47/EEC) CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

**STANDARDS APPLIED:**

ISO 13485: 2016	ISO 10993-5: 2009	ISO 10993-10: 2010
EN 1041: 2008+A1:2013	2011/65/EU	

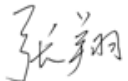


**EUROPEAN REPRESENTATIVE:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, Germany

**START OF CE-MARKING:** 2014-12-09

**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