

# 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:** SPO2 CABLE  
2909-0000004/2909-0000034

**CLASSIFICATION - ANNEX IX:** Class I, Rule 1

**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	EN/ISO 14971: 2012	EN 60601-1: 2006+A1: 2013
EN 60601-1-2: 2015	EN 60601-1-6: 2010+A1:2015	EN 1041: 2008+A1:2013
ISO 80601-2-61: 2017	ISO 15223-1: 2016	ISO 10993-5: 2009
ISO 10993-10: 2010	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