

DECLARATION OF CONFORMITY TO COUNCIL REGULATION (EU) 2017/745 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

SRN OF the MANUFACTURER: CN-MF-000009430

MEDICAL DEVICE: ECG Cable

MODEL: 15010012/15010008/15011920/15010020/15010030

INTENDED USE: The reusable ECG trunk cable and lead wire are used to connect human body (via ECG electrodes) and ECG devices to acquire and transfer ECG signals.

CLASSIFICATION - ANNEX VIII: Class I, Rule 1

BASIC UDI-DI: 69419006ECGcableG8

CONFORMITY ASSESSMENT ROUTE: Annex II+ Annex III

WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL REGULATION (EU) 2017/745 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 15223-1:2021	EN ISO 20417:2021	EN ISO 10993-1:2020
EN ISO 10993-5:2009	EN ISO 10993-10:2013	



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

SRN OF the EUROPEAN REPRESENTATIVE: DE-AR-000000001

PLACE, DATE OF DECLARATION: Shenzhen, Mar.29, 2022

SIGNATURE: 

NAME: Zhang Xiang
POSITION: Management Representative