

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

MANUFACTURER: Shenzhen Creative Industry Co., Ltd.
1001, Building West, Lepu Tower, No.66 Xingke Road,
Xili Community, Xili Street, Nanshan District,
518055 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

SRN OF the MANUFACTURER: CN-MF-000009430

MEDICAL DEVICE: ECG Cable

MODEL: KE-IGB051:15010012/15010020
KE-DGB041:15010080
KE-DGB051:15010073
KE-IGB101: 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