

DECLARATION OF CONFORMITY

COMPLIANCE TO MEDICAL DEVICE REGULATION

2017/745



MANUFACTURER:

NAME: SHENZHEN LAUNCH ELECTRICAL CO. LTD.

ADDRESS: BUILDING F, ZHONGGANGXING INDUSTRIAL ESTATE ZHANGGE
COMMUNITY, GUANIAN STREET, LONGHUA NEW DISTRICT, SHENZHEN
518110, CHINA

SRN: CN-MF-000028780

EUROPEAN REPRESENTATIVE:

NAME: SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE),

ADDRESS: EIFFESTRASSE 80, 20537 HAMBURG, GERMANY

SRN: DE-AR-000000001

MEDICAL DEVICE

ECG LEADWIRES AND TRUNK CABLES

MODELS:

SEE ATTACHED LIST OF DEVICES

CLASSIFICATION - *ANNEX VIII*:

CLASS I, RULE 1

CND CODE:

Z12050385 ELETTROCARDIOGRAFI - MATERIALI SPECIFICI
ELECTROCARDIOGRAPHS - CONSUMABLES

INTENDED PURPOSE

Electrocardiography (ECG or EKG) is the process of recording the electrical activity of the heart over a period of time using electrodes placed on the skin. These electrodes detect the tiny electrical changes on the skin that arise from the heart muscle's electrophysiologic pattern of depolarizing and repolarizing during each heartbeat. Lead wire is used to connect two electrodes which are placed on human body at two different points, it is used to transmit signals to the connected ECG machine and obtained a ECG waveform. During obtaining ECG waveform, the electrode placement and the connection between wire and amplifier is called ECG lead. For single-lead electrocardiographs, the electrocardiogram that showing the body surface electric potential difference, is recorded over several leads over a period of time.

BASIC UDI-DI CODE (GMN) :

69474379DCARLeadwireJF

IDENTIFICATION AND TRACEABILITY:

SEE ATTACHED UDI LIST OF DEVICES

CONFORMITY ASSESSMENT ROUTE:

ANNEX II AND ANNEX III

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE MEDICAL DEVICE REGULATION 2017/745; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER AND EUROPEAN REPRESENTATIVE.

STANDARDS APPLIED:

EN ISO13485:2016+A11:2021, ISO 15223-1: 2021, ISO20417:2021, EN ISO 14971:2019+A11:2021,
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ANSI/AAMI EC53:2013,
DIRECTIVE 2011/65/EU, DELEGATED DIRECTIVE (EU) 2015/863.

START OF CE-MARKING:

2018-07-13

PLACE, DATE OF DECLARATION:

SHENZHEN, 2024/09/12

SIGNATURE:

JINHAI XU

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MANAGEMENT REPRESENTATIVE

WE, AS THE MANUFACTURER, DECLARE UNDER OUR SOLE RESPONSIBILITY FOR THE DECLARATION OF CONFORMITY.

Appendix: List of devices

Item	Models	Product description	BASIC UDI-DI (GMN)	UDI-DI
1	98ME01EC055	5 Lead ECG Electrode leadwires	69474379DCARLeadwireJF	06947437903679
2	98ME01EC057	10 Lead ECG Electrode leadwires	69474379DCARLeadwireJF	06947437903686