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*
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:

ISO13485:2016, ISO 15223-1: 2021, ISO20417:2021, ISO 14971:2019, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021, ANSI/AAMI EC53:2013 IEC60601-2-25:2011 (2ND EDITION), EN 60601-1: 2006/A1:2013+A12:2014, EN 60601-1-2:2015, EN 60601-1-6:2010, EN 62366-1:2015, IEC 60068-2-64:2008, DIRECTIVE 2011/65/EU. DELEGATED DIRECTIVE (EU) 2015/863.

START OF CE-MARKING:	2018-08-07
PLACE, DATE OF DECLARATION:	SHENZHEN, 2025/10/10
SIGNATURE:	JINHAI XU

SHENZHEN LAUNCH ELECTRICAL CO.,LTD
深圳市元和电子材料有限公司

MANAGEMENT REPRESENTATIVE

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

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2017/745

Appendix: List of devices

Item	Models	Product description	BASIC **UDI-DI (GMN)**	**UDI-DI**
1	98ME01EC058B	ECG lead WIRE (10 electrodes button type) IEC	69474379DCARLeadwireJF	06947437903716