

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICE



MANUFACTURER:

SHENZHEN LAUNCH ELECTRICAL CO. LTD. BUILDING F, ZHONGGANGXING
INDUSTRIAL ESTATE ZHANGGE COMMUNITY, GUANIAN STREET, LONGHUA NEW
DISTRICT, SHENZHEN 518110, CHINA

EUROPEAN REPRESENTATIVE:

MDI EUROPA GMBH, LANGENHAGENER STR. 71 D-30855 LANGENHAGEN

MEDICAL DEVICE, MODELS:

REUSABLE ECG ELECTRODES, SEE LIST OF DEVICES

CLASSIFICATION - ANNEX IX:

CLASS I, RULE 1

GMDN CODE:

42489, ELECTRODE, ELECTROCARDIOGRAPH, REUSABLE

CONFORMITY ASSESSMENT ROUTE: ANNEX VII

*WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE
TRANSPOSITION NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING
MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE
MANUFACTURER.*

STANDARDS APPLIED:

EN ISO13485:2012/AC: 2012, ISO 13485: 2003/ COR.1: 2009, DIN EN ISO 13485:2012, ISO
15223-1: 2016, EN ISO 15223-1: 2016, EN1041:2008/A1:2013, EN ISO 14971:2012, ISO
14971:2007/ COR 2007, EN ISO 10993-1:2009/AC:2010, ISO 10993-1:2009, EN ISO
10993-5:2009, ISO 10993-5:2009, EN ISO 10993-10:2013, ISO 10993-10: 2012, EN ISO
10993-12:2012, ISO 10993-12:2012, EN ISO 10993-12:2012, ANSI/AAMI EC12 :2000/(R)2015,
ANSI/AAMI ES60601-1:2005/A1:2012, IEC 60601-1-2-25:2011 (2ND EDITION), IEC
60601-2-27:2011 (3RD EDITION), IEC60601-1:2005 (3RD EDITION)+ CORR.1: 2006+ CORR.2: 2007+
A1:2012, EN 60601-1:2006/A1:2013+ A12: 2014, IEC 60601-1-2: 2014, EN 60601-1-2:2015, IEC
60601-1-6:2010, EN 60601-1-6:2010, EN 62366:2008, IEC 62366:2007, IEC 60068-2-64:2008,
DIRECTIVE 2011/65/EU

START OF CE-MARKING:

2018-07-13

PLACE, DATE OF DECLARATION:

SHENZHEN, 2018.07.13

SIGNATURE:

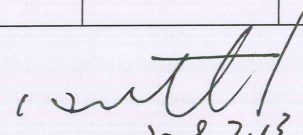
JIAAN HUANG

MANAGEMENT REPRESENTATIVE

WE, AS THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

List of CE-marked Products Reusable ECG Electrodes

S/N	Name of Product	Models	Classification	Rule of classification	GMDN Code
1	REUSABLE ECG ELECTRODES	2104783-001	Class I	MDD Annex IX RULE 1	42489 Electrode, electrocardiograph, reusable
2	REUSABLE ECG ELECTRODES	2104784-001	Class I	MDD Annex IX RULE 1	42489 Electrode, electrocardiograph, reusable
3	REUSABLE ECG ELECTRODES	2104785-001	Class I	MDD Annex IX RULE 1	42489 Electrode, electrocardiograph, reusable

Signature & Date:  20.8.7.13