

# 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, GUANLAN STREET, LONGHUA  
NEW DISTRICT, SHENZHEN 518110, CHINA

EUROPEAN REPRESENTATIVE:

SHANGHAI INTERNATIONAL HOLDING CORP. GMBH(EUROPE)  
EIFFESTRASSE 80, 20537 HAMBURG, GERMANY

MEDICAL DEVICE, MODELS:

TEMPERATURE PROBE, SEE LIST OF DEVICES

CLASSIFICATION - ANNEX IX:

CLASS II A

GMDN CODE:

13125 (PROBES, THERMOMETER)

CONFORMITY ASSESSMENT ROUTE:

ANNEX 2

*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 ISO13485:2016, ISO 13485: 2016, DIN EN ISO 13485:2016, 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, AAMI/ANSI ES60601-1:2005+AMD,  
AAMI/ANSI ES60601-1-2-25 , IEC/EN60601-1, IEC/EN60601-1-2, IEC/EN60601-1-6, EN  
62366:2008, IEC 62366:2007

NOTIFIED BODY

TÜV SÜD PRODUCT SERVICE GMBH,  
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

0123

EC CERTIFICATION NUMBER

No. G1 065652 0010 Rev. 00

START OF CE-MARKING:

2018-08-28

PLACE, DATE OF DECLARATION:

SHENZHEN, 2018.08.28

SIGNATURE:

JIAAN HUANG



MANAGEMENT REPRESENTATIVE

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