

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, GUANLAN 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

REUSABLE TEMPERATURE PROBE

MODELS:

SEE ATTACHED LIST OF DEVICES

CLASSIFICATION - ANNEX VIII:

CLASS IIb, RULE 10

EMDN CODE:

Z1203020285, MULTI-PARAMETER PATIENT MONITORS -
CONSUMABLES

BASIC UDI-DI CODE (GMN) :

SEE ATTACHED LIST OF DEVICES

IDENTIFICATION AND TRACEABILITY:

SEE ATTACHED UDI LIST OF DEVICES

CONFORMITY ASSESSMENT ROUTE:

ANNEX IX CHAPTER I AND 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, EN ISO 15223-1: 2021, ISO20417:2021, EN ISO 14971:2019+A11:2021,
ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-12:2012,
EN ISO 80601-2-56:2017+A1:2020, EN 60601-1: 2006+A2:2021, EN 60601-1-2:2015,
EN 60601-1-6:2010+A2:2021, EN 62366-1:2015+A1:2020, DIRECTIVE 2011/65/EU, DIRECTIVE (EU) 2015/863

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH

RIDLERSTRASSE 65 80339 MUNICH GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

No. G10 065652 0012 REV. 00

START OF CE-MARKING:

2008-07-13

PLACE, DATE OF DECLARATION:

SHENZHEN, 2024.03.15

SIGNATURE:

JINHAI XU

MANAGEMENT REPRESENTATIVE

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

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Appendix: List of devices

Item	Models	Product description	UDI-DI	BASIC UDI-DI (GMN)
1	98ME04GA603	Adult skin temperature probe , with 2.252K resistor	06947437903549	69474379TempPrb-RYV
2	98ME04GA604	Adult rectal temperature probe, with 2.252K resistor	06947437903556	69474379TempPrb242