



Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex V  
(Devices in class I with measuring function)

No. G2M 18 05 04051 002

**Manufacturer:** Hangzhou Long Can Liquid Metal  
Technology Co., Ltd.

1st Floor, Gate 2, No.18 Zhiren Street  
Puyan Binjiang District  
310051 Hangzhou, Zhejiang  
PEOPLE'S REPUBLIC OF CHINA



**EC-Representative:** Prolinx GmbH

Brehmstr. 56  
40239 Duesseldorf  
GERMANY

**Product Category(ies):** Mercury-free Liquid-in-glass Thermometer

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** SH18130401

**Valid from:** 2018-07-13

**Valid until:** 2023-07-12



**Date,** 2018-07-13

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**No. G2M 18 05 04051 002**

**Facility(ies):**

Hangzhou Long Can Liquid Metal Technology Co., Ltd.  
1st Floor, Gate 2, No.18 Zhiren Street, Puyan Binjiang  
District, 310051 Hangzhou, Zhejiang, PEOPLE'S  
REPUBLIC OF CHINA



<b>CE Technical File</b> <b>Mercury-free liquid-in-glass thermometer</b>	File No: LC-TCF-01_6
	Rev. No: A/1

## ***Declaration of Conformity***

**Manufacturer:** Hangzhou Long Can Liquid Metal Technology Co, Ltd.  
1<sup>st</sup> Floor, Gate 2, No. 18 Zhiren Street, Puyan Binjiang District,  
Hangzhou City, Zhejiang Province, China

**European Representative:** **Prolinx GmbH**  
Brehmstr. 56, 40239, Duesseldorf, Germany

**Product Name:** Mercury-free liquid-in-glass thermometer

**Models:** Enclosed-scale(Large, Middle, Small)

**umdns code:** 14028

**Classification (MDD, Annex IX):** I m / Rule 1

**Conformity Assessment Route:** Annex V and Annex V II of Directive 93/42/EEC

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

### DIRECTIVES

**General applicable directives:**

**Medical Device Directive:** COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

**Harmonised standards:** EN ISO 13485:2016, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN ISO 10933-1:2010, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN 12470-1:2000+A1 2009, IEC 62366-1:2015, MEDDEV 2.7.1 Rev 4

**Notified Body:** TÜV SÜD Product Service GmbH, Ridlerstr. 65,  
80339 München, Germany

**NB Identification number:** 0123

**(EC) Certificate(s):** G2M 18 05 04051 002

**Place, Date of Issue:** Hangzhou 2020.4.10

**Signature:**



**Name:** Xu Jianli

**Position:** Management Representative