

# 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

Hangzhou Long Can Liquid Metal Manufacturer:

Technology Co., Ltd.

1st Floor, Gate 2, No.18 Zhiren Street

Puyan Binjiang District 310051 Hangzhou, Zhejiang PEOPLE'S REPUBLIC OF CHINA



**Prolinx GmbH EC-Representative:** 

> Brehmstr. 56 40239 Duesseldorf **GERMANY**

#### **Product** Category(ies):

Date, 2018-07-13

## 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.

SH18130401 Report No.:

2018-07-13 Valid from: 2023-07-12 Valid until:

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123 Page 1 of 2





## **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

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

Page 2 of 2

TÜV







# Certificate

No. Q6 004051 0003 Rev. 00

**Holder of Certificate:** 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

Hangzhou Long Can Liquid Metal Technology Co., Ltd. Facility(ies):

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

See Scope of Certificate

Certification Mark:



Scope of Certificate: **Production and Distribution of** 

Mercury-free Liquid-in-glass Thermometer

EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 004051 0003 Rev. 00

Report No.: SH21130401

Valid from: 2021-07-13

Valid until: 2024-07-12

Christoph Dicks

Head of Certification/Notified Body

Date, 2021-07-06

TÜV®

# CE Technical File Mercury-free liquid-in-glass thermometer

File No: LC-TCF-01\_6

Rev. No: A/1

# Declaration of Conformity

Manufacturer:

Hangzhou Long Can Liquid Metal Technology Co, Ltd.

1st Floor, Gate 2, No. 18 Zhiren Street, Puyan Binjiang District,

Hangzhou City, Zhejiang Province, China

European

Prolinx GmbH

Representative:

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:

Hangshow some 4.10

Signature:

Name:

V. Lianli

Position:

Management Representative

EC Declaration of Conformity LC-TCF-01\_6(A/0)

Page 1/1