ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Digitally signed by Potînga Stela
Date: 2022.05.05 12:15:47 EEST
Reason: MoldSign Signature
Location: Moldova

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

04052768655905

Date, 2018-07-13

Stefan Preiß

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

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

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

See Scope of Certificate

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Mercury-free Liquid-in-glass Thermometer**

Applied Standard(s): EN ISO 13485:2016
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

Date, 2021-07-06

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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 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 2020.04.10

Signature:

Name: Xu Jianli

Position: **Management Representative**