



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire	Введите текст для поиска...										
I.3. Certificatul CE	Certificat CE	Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
I.2. Declarația de conformitate CE	Declarație de Conformitate CE							HANGZHOU LONG CAN LIC	tehoptimed			
		DM000350448	TERMOMETRU FĂRĂ MERCUR		LICHID, DIN STICLĂ, ENCLOSED-SCALE LARGE		China	HANGZHOU LONG CAN LIQUID METAL TECHNOLOGY CO, LTD.	S.A. TEHOPTIMED	Rg04-000122	23-05-2022	
✓ 🔍 Содержит('Reprezentant', 'tehoptimed') и Содержит('Producatorul', 'HANGZHOU LONG CAN LIQUID...') Очистить												

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:



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

C.Dh

Christoph Dicks
Head of Certification/Notified Body

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 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 2022.4.10*

Signature:



Name:

Xu Jianli

Position:

Management Representative



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):

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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

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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