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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 004051 0004 Rev. 01

Manufacturer:

Hangzhou Long Can Liquid Metal Technology Co., Ltd.
1st Floor & 4th Floor, Gate 2, No.18 Zhiren Street
Puyan Binjiang District
310051 Hangzhou, Zhejiang
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000020602

Authorized Representative:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA The Hague, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.
As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G21 004051 0004 Rev. 01

Report No.: SH24130403

Preceding Certificate No.: G21 004051 0004 Rev. 00

Valid from: 2025-06-20
Valid until: 2029-02-07

Date of Initial Issuance: 2024-02-08

Issue date: 2025-06-20

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 004051 0004 Rev. 01

Classification:	Class I
Device Group:	V03010104 - LIQUID EXPANSION THERMOMETERS
Device Properties:	MDS 1010 - Devices with a measuring function
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2024-02-08	SH22130402	Initial issuance
01	2025-06-20	SH24130403	Amended: Change of certificate holder's data

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

CERTIFICATION OF ANALYSIS

According to EN 12470-1-2000+A1-2009 Clinical thermometers Part 1: Metallic liquid-in-glass thermometers with maximum device

Product Name:	Mercury-free Liquid-in-glass Thermometer LIVSANE Liquid-in-glass Thermometer（REF number ： CR 240924， EAN code ： 4062981026543）
Cat:	Enclosed-scale
Quantity:	50000
Manufactured Date:	2024.10.29
Batch No:	24102901
Expiration Date:	5 years

Inspection project	Standard requirements and testing methods	Conclusion
6.1.1 Measuring range and scale interval	The thermometer shall cover the minimum range from 35.5℃ to 42.0℃ with a scale interval of 0.1 ℃	PASS
6.1.2 Scale marks and numbering	The scale marks shall be uniformly spaced and of uniform width. The scale marks and numbers shall be at right angles to the axis of the thermometer and shall be visible at the same time as the liquid column.	PASS
6.1.2.2 Scale spacing	The distance between adjacent scale marks shall be at least 0,6 mm for enclosed-scale thermometers.	PASS
6.1.2.3 Width and length of the scale marks	The scale marks shall be durably marked and shall be of uniform width not exceeding one-fifth of the length of a scale spacing plus 0,05 mm for enclosed-scale thermometers. Scale marks representing whole degrees and half degrees shall be longer than the other scale marks.	PASS
6.1.2.4 Numbering	Scale marks representing whole degrees shall be numbered. NOTE The scale mark representing the temperature of 37℃ can be rendered conspicuous by means of a different colour from that used for the numbering and/or by additional marking.	PASS

6.1.2.6 Special requirements for enclosed-scale thermometers	The thermometer shall have a separate scale panel adjacent to the capillary tube. The capillary tube and the scale panel shall be enclosed in a transparent tube impermeably fixed to the bulb and forming a protection sheath. The scale shall be marked on a scale panel fixed longitudinally behind the capillary tube.	PASS
6.1.2.7 Resistance to breakage of enclosed-scale thermometers	The thermometer shall not break when subjected to a force of at least 50N in accordance with 7.8.	PASS
6.2.3 Scale panel of enclosed-scale thermometer	The scale panel of enclosed-scale thermometers shall be of opal glass, metal or another material of a dimensional stability such that, when tested in accordance with 7.4, the length of the scale sample after heating shall not differ from that before heating by more than 0,2 %.	PASS
6.2.4 Thermometric liquid filling	The metallic liquid filling used in the thermometer shall have the purity, properties and characteristics that will enable the finished thermometers to comply with all requirements specified in this European Standard. The bulb, the capillary tube and the liquid column of the finished thermometer shall be free of gas, water, glass fragments or other foreign material.	PASS
6.3.1 Freedom from defects	The thermometer and its surface shall be free from defects that are likely to interfere with its proper functioning or to mislead the user, e.g. errors in graduation, flaws in the glass and constructional defects.	PASS
6.3.2 Capillary tube	The capillary tube shall ensure that the entire length of the liquid column and the meniscus are clearly visible from at least one angle. It shall be prismatic in form and have a magnifying effect, or shall be so designed as to ensure consistent ease of reading.	PASS

6.3.3 Thermometer ends	The ends of the thermometer shall be smoothly rounded in order to prevent tissue damage during use.	PASS
6.3.4 Liquid column	When the thermometer is heated slowly, the liquid column shall rise uniformly without appreciable surges. NOTE Surges larger than half a scale interval are considered as defects.	PASS
6.3.5 Scale panel of enclosed-scale thermometer	The scale panel shall be either directly fixed to the capillary tube or be in direct contact with the capillary tube and fixed sufficiently firmly in the sheath to prevent any displacement with respect to the capillary tube. The scale panel shall be so positioned as to ensure that any displacement can be easily detected either by means of an indelible mark on the sheath level with a numbered scale mark or by some equivalent means. The marking shall be in accordance with 6.1.2.3 and shall be placed at 38 ℃ with a lateral tolerance of one-fifth of a scale spacing. The sheaths of enclosed-scale thermometers shall be free of moisture, liquid, glass fragments and foreign material.	PASS
6.5 Maximum permissible error under reference conditions	Within the measuring range specified in 6.1.1 the maximum permissible error of the thermometer shall be + 0,1 ℃ and - 0,1 ℃. This value applies to the stabilized thermometer readings.	PASS

Conclusion: ☑Qualified ☐Fail

Quality Department: Chen yunbo DATE:2024.10.29

EU Declaration of Conformity

According to ANNEX IV of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

Name: Hangzhou Longcan Liquid Metal Technology Co., Ltd.

Address:

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

Tel: +86-571-28217811

Email: zlz@hzlongcan.com

SRN: CN-MF-000020602

杭州龙灿液态金属科技有限公司
Hangzhou Longcan Liquid Metal Technology Co., Ltd.

Whose Europe Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

SRN: NL-AR-000000121

We, the manufacturer, herewith declare that the product(s)

Product Name	Mercury-free Liquid-in-glass Thermometer (LIVSANE Liquid-in-glass Thermometer REF number ： CR 240924， EAN code ： 4062981026543)	**Model**	Enclosed-Scale
Basic UDI-DI	**697122248ThermometerY6**	**EMDN**	V03010104
Intended Use	Mercury-free liquid-in-glass thermometer for measuring body temperature under the armpit.		
Classification	Class I_m, Rule 1 of MDR Annex VIII		

meet(s) the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Annex XI Part A Production Quality Assurance.

Applicable Standards and CS:

ENISO13485:2016
EN ISO 14971:2019
EN ISO 10993-1: 2020
ISO 10993-23:2021
EN 12470-1:2000+A1:2009
ISO 20417:2021
ISO 10993-5:2009
EN 62366-1:2015
EN 15223-1:2016
ISO 10993-10:2021

Metrological requirements: Within the measuring range of 35.5~42℃, the maximum permissible error of the thermometer shall be + 0,1 ℃ and - 0,15 ℃.

The aforementioned device has been assigned to class I_m according to Annex VIII of the Regulation (EU) 2017/745, and is certificated by notified body TUV SUD Product Service GmbH Ridlerstr.65,80339 Munchen, Germany(Notified Body identification Number: 0123) with certification number G21 004051 0004 Rev. 00, which means it bears the CE mark

CE 0123

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745.

The above-mentioned declaration of conformity is exclusively under the responsibility of

Hangzhou Longcan Liquid Metal Technology Co., Ltd.

Name of General Manager	He Huxing
Signature	
Date	2024-05-13
Place	Hangzhou, Zhejiang Province, China
Seal (Manufacturer)	