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Precisely Right.

2023-11-21

**To Whom It May Concern**

Applicant: Hangzhou Universal Electronic Co., Ltd.

Address: 298 Yunxi Road, Cangqian Street, Yuhang District, Hangzhou, 311121 Zhejiang, P.R. China

MDRScope: Products of class IIa:
V030101-CONTACT DIGITAL THERMOMETERS
-Digital thermometer（MDA 0204）
V030101- NON-CONTACT DIGITAL THERMOMETERS
- Infrared thermometer（MDA 0204）
Z120302- NON-INVASIVE OSCILLOMETRIC BLOOD PRESSURE GAUGES
- Blood pressure monitor（MDA 0204）

Standards: MDR 2017/745, Annex IX, Chapter I

The Certification quotation is under approval.

Yours sincerely,
TÜV RHEINLAND (SHANGHAI) Co., Ltd.

Tony Chen

Mr. Tony Chen
Location Field Manager
Greater China, Medical Services

TÜV Rheinland
(Shanghai) Co., Ltd.

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HangZhou Universal Electronic Co,. Ltd
Tel:86-571-88308205 Email :info@chinaguangfa.com

**Declaration**

We, HangZhou Universal Electronic Co,. Ltd. with registered seat: No. 298 Yunxi Road Cangqian Street, Yuhang District HangZhou, 311121 ZheJiang, China (hereinafter: the "**Manufacturer**"), Tel:86-571-88308205 Email:info@chinaguangfa.com ,declare that the MDD - EC certificate: registration no: DD 60133013 0001, issued by notified body TÜV Rheinland LGA Products GmbH (0197) in accordance with the Annex V of the Directive 93/42/EEC (hereinafter: the "**Certificate**"), respectively: has indicated its expiry date: 6.11.2023 and has not been withdrawn by above mentioned notified body.

Pursuant to the Article 120(2) of the Regulation (EU) 2017/745 on medical devices in connection with the Article 120(3a) point b) and the Article 120(3c) of this Regulation, the Certificate has its extended validity done automatically by the law.

The medical devices covered by the extension of the transitional period and the Certificate are in particular including: **"Digital Thermometer; Infrared Thermometer ;Digital Blood Pressure Monitor** (hereinafter: the "**medical devices**").

The Manufacturer confirms and guarantees that all conditions for the extension of the Certificate validity and for the extension of the transitional period regarding above mentioned medical devices, indicated in the Regulation (EU) 2017/745 on medical devices, in particular laid down in its Article 120(3c), are fulfilled:

a) The above mentioned medical devices continue to comply with the Directive 93/42/EEC;
b) There are no significant changes in the design and intended purpose regarding the above mentioned medical devices;
c) The above mentioned medical devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
d) HangZhou Universal Electronic Co,. Ltd. (the Manufacturer) currently no later than 26 May 2024 will put in place and will implement a quality management system in accordance with the Regulation (UE) 2017/745 on medical devices and due to the Article 10(9) of this Regulation;
e) HangZhou Universal Electronic Co,. Ltd. (the Manufacturer) no later than 26 May 2024 will submit a formal MDR certification application to the notified body, in particular in accordance with Section 4.3, first subparagraph of Annex VII of the Regulation (UE) 2017/745 on medical devices for conformity assessment in respect of the above mentioned medical devices. The Manufacturer also confirms that the above mentioned notified body and the Manufacturer no later than 26 September 2024 will sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of the above mentioned Regulation.

Jiang Fuzheng

In view of the above, the Manufacturer confirms and guarantees that all legal, regulatory and safety and quality requirements for the above mentioned medical devices have been met and the end date of the Certificate validity as well as the end date of the transition period for the above mentioned medical devices is: 31 December 2028. Until that date presented in previous sentence, the above mentioned medical devices (each of them) may be legally placed on the market and put into service within the territory of the EU and individual Member States.

Hangzhou 2023.10.31

Place/Date

Jiang Ruizhong
General manager

Name and Function

杭州广发电子技术有限公司
Hangzhou Universal Electronic Co.,Ltd

**Business Stream Products**
Certification Department

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LGA
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TÜV Rheinland LGA Products GmbH • 51105 Köln

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298 Yunxi Road, Cangqian Street, Yuhang District,
Hangzhou, 311121 Zhejiang, China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date September 20, 2023

Dear valued customer,

thank you for getting back to us in the question on the confirmation of extension of existing MDD certificates bound to expire shortly or already expired after March 20, 2023 (date of publication of the Regulation (EU) 2023/607 within the European Journal).

In the context of the cited regulation, all MDD certificates that were valid on March 20, 2023 are extended until end of December 2027 resp. 2028 (depending on the risk class of the devices in question) by law. The understanding is that the dates mentioned within the amending regulation override the expiration dates mentioned on the individual certificates. There are certain actions that need to be undertaken by medical device manufacturers and Notified Bodies to allow the extension to be maintained prior to the final expiration dates mentioned within the regulation. A formal extension application for individually listed products by the manufacturers must be filed by May 26, 2024. By then legal manufacturers of medical devices must also have updated their quality management system to comply with all requirements as defined in Regulation (EU) 2017/745, also referred to as Medical Device Regulation MDR. By September 2024, a written agreement between legal manufacturers and their Notified Bodies needs to be established on the consensus of maintaining devices on the market and to transition them from the certification under the Medical Device Directive 93/42/EEC (also referred to as MDD) to certification under the Medical Device Regulation MDR within the time frames defined in the amending regulation (EU) 2023/607.

The amending regulation does not see the need for a letter from behalf of Notified Bodies to their customers that confirms the validity of certificates expiring between March 20, 2023 and May 25, 2024, as the validity is already stated within the regulation (EU) 2023/607.

We are aware that the extension of certificates by law is an unusual procedure, especially if an individual certificate expires prior to May 26, 2024 (or has already expired but was still valid on March 20, 2023). The expectations are nevertheless that this understanding becomes overall consent, and TÜV Rheinland herewith confirms that for all our customers where above said conditions are met, MDD certificates remain valid under the Regulation (EU) 2023/607. In case of any further questions or comments please do not hesitate to contact us.

We appreciate your understanding and your business. Sincerely,

On behalf of the Notified Body

Herbert Zhong
Certification body

TÜV Rheinland
LGA Products GmbH

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Germany

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# EC Certificate

## Directive 93/42/EEC Annex V
## Production Quality Assurance
## Medical Devices

**Registration No.:** DD 60133013 0001

**Report No.:** 15067271 006

**Manufacturer:**

Hangzhou Universal
Electronic Co., Ltd.
298 Yunxi Road, Cangqian Street
Yuhang District
Hangzhou
311121 Zhejiang
China

**Products:**

- Digital Thermometers
- Blood Pressure Monitors
- Infrared Ear Thermometers
- Infrared Forehead Thermometers
- Infrared Ear / Forehead Thermometers

Replaces Approval, Registration No.: DD 60110599 0001

**Expiry Date:** 2023-11-06

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2019-08-08

**Date:** 2019-08-08

Notified Body

Herbert Zhong

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.