

## **EC** Certificate

## Directive 93/42/EEC Annex II, excluding Section 4 Full Quality Assurance System Medical Devices

Registration No.: HD 60148105 0001

Report No.: 10052841 014

Manufacturer: K-jump Health Co., Ltd.

No. 56, Wu Kung 5th Rd. New Taipei Industrial Park New Taipei City, 24890

**Taiwan** 

Products: Medical Devices

(see attachment for products and sites included)

Replaces Approval, Registration No.: HD 60144083 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2020-07-28

**Date:** 2020-07-28

**Notified Body** 

Dipl.-Ing. W. Hsu

TÜVRheinland

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.



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.: HD 60148105 0001 Report No.: 10052841 014

Manufacturer:

K-jump Health Co., Ltd. No. 56, Wu Kung 5th Rd. New Taipei Industrial Park New Taipei City, 24890 Taiwan

## Products:

- Clinical Electronic Thermometers
- Infrared Thermometers (Ear & Forehead)
- Non-Invasive Electronic Sphygmomanometers (Blood Pressure Meters)
- Nebulizers
- Peak Flow Meters

## Sites included:

K-jump Health Co., Ltd. No. 56, Wu Kung 5th Road, New Taipei Industrial Park, New Taipei City 24890, Taiwan

Dongguan Polygreen Technology Co., Ltd.
Room 101, Building 1, No.19, Tianxing Road,
Huangjiang Town, Dongguan City,
Guangdong Province, China

Date: 2020-07-28

Dipl.-Ing. W. Hsu