

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2072615-1

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

Scope: Design and Development, Manufacture and Distribution of
Clinical Electronic Thermometers, Infrared Thermometers (Ear
& Forehead), Non-Invasive Electronic Sphygmomanometers,
Nebulizers and Peak Flow Meters for the area of
anaesthesiology;
Design and Development, Manufacture and Distribution of in
vitro diagnostic medical devices used in the monitoring of
blood glucose including self-testing in vitro diagnostic devices

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 48249290-070

Effective date: 2025-02-01

Expiry date: 2028-01-31

Issue date: 2025-01-22

Replaces certificate SX 2072615-1 issued 2023-11-01

This certificate can be validated on <https://www.certipedia.com>


Yuhong Chen

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o K-jump Health Co., Ltd. No. 56, Wu Kung 5th Rd., New Taipei Industrial Park, New Taipei City 24890 Taiwan	Design and Development, and Distribution of Clinical Electronic Thermometers, Infrared Thermometers (Ear & Forehead), Non-Invasive Electronic Sphygmomanometers, Nebulizers; Design and Development, Manufacture and Distribution of Peak Flow Meters for the area of anaesthesiology; Design and Development, Manufacture and Distribution of in vitro diagnostic medical devices used in the monitoring of blood glucose including self-testing in vitro diagnostic devices
/02	c/o Dongguan Polygreen Technology Co., Ltd. Room 101, Building 1, Room 201, 301, 401, 501, Building 2, No.19, Tianxing Road, Huangjiang Town, Dongguan City, Guangdong Province, P.R. China	Manufacture of Clinical Electronic Thermometers, Infrared Thermometers, Non-Invasive Electronic Sphygmomanometers and Nebulizers

This certificate can be validated on <https://www.certipedia.com>