

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2095316-1

Certificate Holder: Hangzhou Hua'an Medical & Health Instruments Co., Ltd.
Building 2, 1# Fuzhu Nan RD,
Wuchang Town, Yuhang District,
Hangzhou
310023 Zhejiang
P.R. China

Scope: Design and Development, Manufacture and Distribution of
Digital Thermometers, Infra-red Ear Thermometers, Digital
Blood Pressure Monitors (Digital Sphygmomanometers), Infra-
red Forehead Thermometers

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.: 326056263-200

Effective date: 2025-02-17

Expiry date: 2028-02-16

Issue date: 2025-01-22

Replaces certificate SX 2095316-1 issued 2023-03-15



Fuxiu Sheng

TÜV Rheinland LGA Products GmbH

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Hangzhou Hua'an Medical & Health Instruments Co., Ltd. Building 2, 1# Fuzhu Nan RD, Wuchang Town, Yuhang District, Hangzhou 310023 Zhejiang P.R. China	Aspects related to Design and Development, Manufacture and Distribution
/02	c/o Huai An Hua Lve Electronics Co., Ltd. No.211 Yingchun Avenue, Xucheng Industrial Zone, Xuyi, Huai'an City, 211700 Jiangsu P.R. China	Aspects related to Manufacture

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