

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

Registration No.: DD 60147728 0001

Report No.: 15095961 011

Manufacturer: JOYTECH Healthcare Co., Ltd.
No. 365, Wuzhou Road
Yuhang Economic Development Zone
Hangzhou City
311100 Zhejiang
P.R. China

Products:

- Digital Thermometers
- Blood Pressure Monitors
- Infrared Ear Thermometers
- Infrared Forehead Thermometers
- Infrared Ear/Forehead Thermometers
- Electric Breast Pumps

Replaces Approval, Registration No.: DD 60128148 0001

Expiry Date: 2024-05-26

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: 2020-04-07

Date: 2020-04-07

Notified Body

Jason Pan



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.

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2018581-1

Organization: JOYTECH Healthcare Co., Ltd.
No. 365, Wuzhou Road
Yuhang Economic Development Zone
Hangzhou City
311100 Zhejiang
P.R. China

Scope: Design and Development, Manufacture and Distribution of Digital Thermometers, Blood Pressure Monitors, Infrared Ear Thermometers, Infrared Forehead Thermometers, Infrared Ear/Forehead Thermometers, Electric Breast Pumps, Manual Breast Pumps, Finger Pulse Oximeter

TÜVRheinland®

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.: 244410547-200
Effective date: 2022-07-11
Expiry date: 2025-07-10
Issue date: 2022-06-28



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
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