

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

Registration No.: DD 60137410 0001

Report No.: 15067822 017

Manufacturer: Hangzhou Sejoy Electronics &

Instruments Co., Ltd.

Building 2, No. 202, Zhenzhong Road West Lake Economy & Technology Zone

310030 Hangzhou

China

Products: Medical Devices

(see attachment for products and additional site included)

Notified Bods

Fuxiu Sheng

Replaces Approval, Registration No.: DD 60116029 0001

Expiry Date: 2024-05-27

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: 2019-06-03

Date: 2019-06-03

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.



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.: Report No.:

DD 60137410 0001

15067822 017

Manufacturer:

Hangzhou Sejoy Electronics &

Instruments Co., Ltd.

Building 2, No. 202, Zhenzhong Road West Lake Economy & Technology Zone

310030 Hangzhou

China

Products:

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

Site included:

No.3, 1st Street, Yuhang Economic Development Zone, Hangzhou 311100, China

Manufacture of Digital Thermometers, Infra-red Ear Thermometers, Blood Pressure Monitors, Infrared Ear/Forehead Thermometers

Date: 2019-06-03

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