

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

Registration No.: DD 60149966 0001

Report No.: 15067822 020

Manufacturer: Hangzhou Sejoy Electronics &

Instruments Co., Ltd.

Area C, Building 2, No.365, Wuzhou Road

Yuhang Economic Development Zone

Hangzhou City 311100 Zhejiang

P.R. China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: DD 60137410 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:

2020-09-08

Date:

2020-09-08

Herbert Zhong

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.:

DD 60149966 0001

15067822 020

Manufacturer:

Report No.:

Hangzhou Sejoy Electronics &

Instruments Co., Ltd.

Area C, Building 2, No.365, Wuzhou Road

Yuhang Economic Development Zone

Hangzhou City 311100 Zhejiang

P.R. China

Products:

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

Site included:

Hangzhou Sejoy Electronics & Instruments Co., Ltd. Building 2, No.202, Zhenzhong Road, West Lake Economy & Technology Zone, Hangzhou 310030, China

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

Date: 2020-09-08

Notified Bod Herbert Zhong Pertifizier