

**EC Declaration of Conformity***Manufacturer:***Hangzhou Sejoy Electronics &.Instruments Co.,  
Ltd.**Address1:Building 2, No. 202, Zhenzhong Road,  
West Lake Economy & Technology Zone, Hangzhou,  
ChinaAddress2:No.3,1st Street,YuHang Economic  
Development Zone,Hangzhou ,China

We, the manufacturer, herewith declare that the products

Product Name: Blood Pressure Monitor (Ciśnieniomierz automatyczny DEPAN)

Model: BSP-11

Client item No.: 01003031

UMDNS-Code: 16173

*whose single Authorized Representative:***Shanghai International Holding Corp.  
GmbH (Europe)**

Eiffestrasse 80, 20537 Hamburg, Germany

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **IIa** by **rule 10** according to Annex IX of the Directive 93/42/EEC. It bears the mark

The product concerned has been evaluated under technical files compliance according to Annex VII, and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body.

**TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2, 90431, Nürnberg, Germany**  
Certificate No.: DD 60137410 0001  
Issue date: 2019-06-03  
Expiry date: 2024-05-27

following the procedure relating to the EC Declaration of Conformity set out in Annex V and Annex VII of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Hangzhou Sejoy Electronics &amp;.Instruments Co., Ltd.

Address1: Building 2, No.202, Zhenzhong Road, West Lake Economy &. Technology Zone,  
HangZhou, ChinaAddress2: No.3,1<sup>st</sup> Street,Yuhang Economic Development Zone,Hangzhou 311100,China**Hangzhou June, 2019***Place , date**Legally binding signature, Function*杭州世佳电子有限公司  
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.

**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)  
  
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

Notified Body



Fuxiu Sheng

**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**

**Attachment to  
Certificate**

**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:**

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

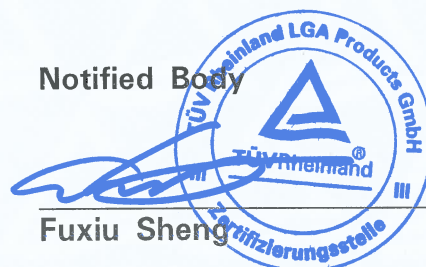
**Site included:**

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

**Notified Body**



**Fuxiu Sheng**

## EC Declaration of Conformity

*Manufacturer:*

**Hangzhou Sejoy Electronics & Instruments Co., Ltd.**

Address1: Building 2, No. 202, Zhenzhong Road,  
West Lake Economy & Technology Zone, Hangzhou,  
China

Address2: No.3, 1st Street, YuHang Economic  
Development Zone, Hangzhou, China

We, the manufacturer, herewith declare that the products

**Product Name:** Blood Pressure Monitor

**Model:** BSP-11, BP-2116

*UMDNS-Code:* 16173

*whose single Authorized Representative:*

**Shanghai International Holding Corp.  
GmbH (Europe)**

Eiffestrasse 80, 20537 Hamburg, Germany

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class **Ila** by **rule 10 according** to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been evaluated under technical files compliance according to Annex VII, and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body.

**TÜV Rheinland LGA Products GmbH  
Tillystraße 2, 90431, Nürnberg, Germany**

Certificate No.: DD 60137410 0001

Issue date: 2019-06-03

Expiry date: 2024-05-27

following the procedure relating to the EC Declaration of Conformity set out in Annex V and Annex VII of Directive 93/42/EEC.

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The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Hangzhou Sejoy Electronics & Instruments Co., Ltd.

Address1: Building 2, No.202, Zhenzhong Road, West Lake Economy & Technology Zone,  
Hangzhou, China

Address2: No.3, 1<sup>st</sup> Street, Yuhang Economic Development Zone, Hangzhou 311100, China

**Hangzhou June, 2019**

*Place, date*



*Legally binding signature, Function*

杭州世佳电子有限公司  
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO., LTD.