

## 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: 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.

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 & Instruments Co., Ltd.

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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.