

**DECLARATION OF CONFORMITY**

**TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING  
MEDICAL DEVICES**

Manufacturer: Shenzhen Pacom Medical Instruments Co.,Ltd

On the eighth floor of B District, B Building, No 5 Industry Five road, Jiangbian Community. Songgang, Baoan District, Shenzhen, P.R China  
Medical Device: Termometr bezdotykowy DEPAN / Non-contact Infrared Body thermometer

Model: 01004011/PC868

CLASSIFICATION-ANNEX IX: CLASS II A, RULE 10

CONFORMITY ASSESSMENT ROUTE: ANNEX II (Excluding section 4)

WE, Shenzhen Pacom Medical Instruments Co.,Ltd., HEREWITH DECLARE THAT

THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES ; INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

THE COMPANY FOLLOWS THE PROCEDURE OF CONFORMITY DESCRIBED IN THE ANNEX 2 EXCLUDING SECTION 4 OF MENTIONED DIRECTIVE AND ARE IN CONFORMIT WITH THE NATIONAL HARMONISED STANDARDS.

NOTIFIED BODY: SGS FIMKO OY

P.O.BOX 30(Sarkiniementie 3)00211 HELSINKI Finland

Phone: +3589696361 Fax: +35896925474

Email: [sgs.fimko@sgs.com](mailto:sgs.fimko@sgs.com) Website: [www.fi.sgs.com](http://www.fi.sgs.com)



IDENTIFICATION NUMBER

(EC)CERTIFICATE(S):

**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



**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

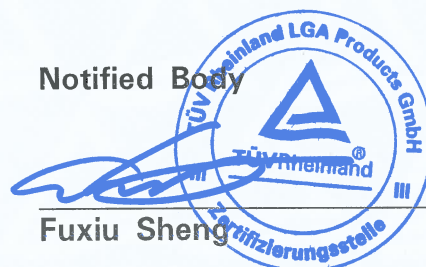
**Site included:**

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**

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg Germany

**Tel:** 0049-40-2513175 **Fax :** 0049-40-255726

START OF CE-MARKING: ISSUE DATE OF EC CERT

PLACE, DATE OF DECLARATION: CHINA GUANGDONG PROVINCE 20190731

SIGNATURE:

