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 ChinaMedical 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 COUNCILO 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 DOCUMENTSTION 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.0.BOX 30(Sarkiniementie 3)00211 HELSINKL Finland

Phone: +3589696361 Fax: +35896925474

Email: sgs.fimko@sgs.com Website: www.fi.sgs.com

IDENTIFICATION NUMBER CE 0598

(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.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

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

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® III Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-06-03

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: