

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4 Full Quality Assurance System Medical Devices

Registration No.: HD 60146953 0001

Report No.: 17061667 011

Manufacturer: Shenzhen Pango Electronic Co., Ltd.

No. 25, 1st Industry Zone Fenghuang Road, Xikeng Village Henggang Town, Longgang District

Shenzhen

518115 Guangdong

P.R. China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60129178 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date:

2020-02-18

Date:

2020-02-18

TÜV Rheinland LGA Products GmbH - Tillystraße 200431 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

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HD 60146953 0001

Report No.:

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No. 25, 1st Industry Zone

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Shenzhen

518115 Guangdong

P.R. China

Products:

- Intermittent pneumatic compression units
- Infrared Ear Thermometers
- Infrared Forehead Thermometers
- Infrared Ear/Forehead Thermometers

Site included:

2-4 Floor, No.5 Shanzhuang Rd., Xikeng Village, Henggang Town, Longgang District, Shenzhen City, Guangdong Province, China

Date: 2020-02-18

Notified Body

TÜVRheinlesselle

Jing Zhang

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