

## **EC** Certificate

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

Registration No.: HD 2101948-1

Manufacturer: Shenzhen Pango Medical Electronics

Co., Ltd

No.25, 1st Industry Zone,

Fenghuang Road, Xikeng Village, Henggang Town, Longgang District

Shenzhen

518115 Guangdong

P.R. China

Products: Intermittent pneumatic compression units, Infrared Ear Thermometers,

Infrared Forehead Thermometers, Infrared Ear/Forehead Thermometers

# TUVRheinland

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.

Report No.: 10918551-100

Effective date: 2021-04-08

Expiry date: 2024-05-26

Issue date: 2021-04-08

TÜVRheinland III Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



## **EC** Certificate

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

Registration No.:

HD 2101948-1

Manufacturer:

Shenzhen Pango Medical Electronics

Co., Ltd

No.25, 1st Industry Zone.

Fenghuang Road, Xikeng Village, Henggang Town, Longgang District

Shenzhen

518115 Guangdong

P.R. China

The scope of certification includes the following manufacturing sites:

### No. Location

/01

Shenzhen Pango Medical Electronics

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

518115 Guangdong

P.R. China

### Product groups manufactured

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

Report No.: 10918551-100

Effective date: 2021-04-08

Expiry date: 2024-05-26

Issue date: 2021-04-08 TÜVRheinlan pl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.