



TÜVRheinland®

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

Registration No.: HD 60110846 0001

Report No.: 17058617 001

Manufacturer: Shenzhen Dongdixin Technology
Co., Ltd.
No. 3 Building XiliBaimang
Xusheng Industrial Estate
518108 Nanshan, Shenzhen
China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60106395 0001

Expiry Date: 2021-06-21

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: 2016-06-22

Date: 2016-06-20



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.: HD 60110846 0001
Report No.: 17058617 001

Manufacturer: Shenzhen Dongdixin Technology
Co., Ltd.
No. 3 Building XiliBaimang
Xusheng Industrial Estate
518108 Nanshan, Shenzhen
China

Products:

- Clinical Electronic Thermometers
- Infrared Ear/Forehead Thermometers
- Infrared Ear Thermometers
- Infrared Forehead Thermometers
- Nerve and Muscle Stimulators
- Electrical Acupuncture Stimulators
- Transcutaneous Electrical Nerve Stimulators
- Electrical Muscle Stimulators
- Electrical Neuromuscular Incontinence Stimulators
- Ultrasound Physical Therapy Devices
- Ultrasound and Electrical Neuromuscular Stimulators
- Magnetic Stimulators
- Electromagnetic Stimulators
- Stimulation Electrodes
- Electromyograph (EMG) Biofeedback Device
- Electromyograph (EMG) Biofeedback and
Neuromuscular Stimulator
- Shortwave Therapy Devices
- Laser Therapy Devices

Date: 2016-06-20

Notified Body



S. Li

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60110846 0001
Report No.: 17058617 001

Manufacturer: Shenzhen Dongdixin Technology
Co., Ltd.
No. 3 Building XiliBaimang
Xusheng Industrial Estate
518108 Nanshan, Shenzhen
China

Site included:

Block A, 5th floor, FUHUA Technic Building, NO.9116 BEIHUAN
Road, 518057, Nanshan District, Shenzhen, China

Activities related to design and development

Date: 2016-06-20

Notified Body

