

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

Registration No.: HD 60147882 0001

Report No.: 17057653 014

Manufacturer: Shenzhen Dongdixin Technology
Co., Ltd.
Floor 1-2, No.3 Building,
Fanshen Xusheng Industrial Estate
Xilixiaobaimang
518108 Nanshan District, Shenzhen
P.R. China

Products: Medical Devices
(see attachment for products and additional sites included)
Replaces Approval, Registration No.: HD 60138391 0001

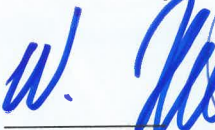
Expiry Date: 2024-05-26

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: 2020-08-03

Date: 2020-08-03

Notified Body


Dipl.-Ing. W. Hsu



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**

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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: 2020-08-03

Notified Body


Dipl.-Ing. W. Hsu



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Xilixiaobaimang
518108 Nanshan District, Shenzhen
P.R. China


Sites included:

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

Floor 1, No.2 Building, Xinjianxing Industrial Estate,
Yangguang 2nd Road, Nanshan District,
Shenzhen 518108, China

Date: 2020-08-03

Notified Body


Dipl.-Ing. W. Hsu

