EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60146168 0001

Report No.: 17049711 010

Manufacturer:
SHENZHEN SUPERLINE
TECHNOLOGY CO., LTD.
Room 1206, Building 4
Chongwen Garden,Taoyuan Street
Nanshan District
Shenzhen
518055 Guangdong
P.R. China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: DD 60132426 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2020-02-13

Date: 2020-02-13

Notified Body

TÜV Rheinland LGA Products GmbH

Jing Zhang

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.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60146168 0001
Report No.: 17049711 010

Manufacturer:
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518055 Guangdong
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Products:

- Orthodontic Wires
- Dental Root-canal Instruments
- Gutta-percha Points
- Sterile Absorbent Paper Points
- Orthodontic Brackets

Site included:

5F-8F, Bldg. A, Zone C, Shiwei Datianyang Ind. Park,
Jiangshi Community, Guangming, Shenzhen, 518105 China

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-02-13

Jing Zhang