

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

**Registration No.:** DD 60141632 0001

**Report No.:** 15049157 009

**Manufacturer:** Shanghai Zogear Industries  
Co., Ltd.  
Suite 303, Building 4  
No. 406 Kang Yi Road, Kang Qiao Town  
Pudong New District  
201315 Shanghai  
P.R. China

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: DD 60117259 0001

**Expiry Date:** 2022-01-17

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:** 2020-03-19

**Date:** 2020-03-19

Notified Body

Herbert Zhong



**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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**Report No.:** 15049157 009

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**Products:**

Disposable Syringes, Sterile Dental Needles for Single Use,  
Root Canal Instruments, Gutta Percha Points, Sterile  
Absorbent Paper Points, Dental Cements Series,  
Diamonds Burs, Ceramic Grinders, High Speed Air  
Turbine Dental Handpieces, Low Speed Dental Handpieces,  
Dental Units, Sterile Surgical Blades, Ultrasonic Scalers,  
Orthodontic Brackets, Orthodontic Bands, Orthodontic Wires,  
Orthodontic Adhesives, Sterile Suture Needles with Thread

Aspects of manufacture concerned with securing  
and maintaining sterile conditions:

Sterile Dental Cotton Rolls, Sterile Gauze Sponges,  
Sterile Cotton Tip Applicators, Sterile Non-Woven Sponges,  
Sterile Cotton Balls, Non-Woven Surgical Gowns,  
Face Masks, Non-Woven Caps, Rubber Polishers, Irrigation  
Sets, Sterile Surgical Packs, Sterile Dental Kits

**Date:** 2020-03-19

**Notified Body**

**Herbert Zhong**

