

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**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

has established and applies a quality management system for medical devices
for the following scope:

**Manufacture and Distribution of
Medical Devices**
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-04-13
Certificate Registration No.: SX 60144469 0001
An audit was performed. Report No.: 15049157 011
This Certificate is valid until: 2022-11-08

Certification Body



Date 2020-04-13


Herbert Zhong


TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60144469 0001
Report No.: 15049157 011

Organization: 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

Scope:

Products:

Disposable Syringes, Sterile Dental Needles for Single Use, Root canal instruments, Gutta Percha Points, Sterile Absorbent Paper Points, Dental Cements series, Diamond Burs, Ceramic Grinders, High speed Air Turbine Dental Handpieces, Low Speed Dental handpieces, Dental Units, Sterile Surgical Blades, Sterile Suture Needles with Thread, Ultrasonic Scalers, Orthodontic Brackets, Orthodontic Bands, Orthodontic Wires, Orthodontic Adhesives, 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, LED Light Curing Devices, Disposable Dental Bibs, Air Compressors, Medical X-ray Protective Clothes, Micro Applicators

Certification Body



Date: 2020-04-13

Herbert Zhong



Business Stream Products
Certification Department



TÜVRheinland®

LGA

Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shanghai Zogear Industries
Co., Ltd.
Suite 303, Building 4
No. 406 Kang Yi Road, Kang Qiao Tow
Pudong New District
201315 SHANGHAI
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date April 14, 2020

Application for : QMS
Certificate No. : SX 60144469 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. SX 60144469 0001.

Kind regards

Certification body

Herbert Zhong

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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