

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Raysen (Tianjin) Healthcare  
Products Co., Ltd.**  
No. 3, Huanyuxi Road, Tianyu Technology  
Park, Jinghai District  
301609 Tianjin  
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: 2020-02-19  
Certificate Registration No.: SX 60143691 0001  
An audit was performed. Report No.: 16806293 006  
This Certificate is valid until: 2022-08-17

Certification Body



Date 2020-02-19



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety

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

**Attachment to  
Certificate**

**Registration No.:** SX 60143691 0001  
**Report No.:** 16806293 006

**Organization:** Raysen (Tianjin) Healthcare  
Products Co., Ltd.  
No. 3, Huanyuxi Road, Tianyu Technology  
Park, Jinghai District  
301609 Tianjin  
P.R. China

**Scope:**

**Products:**

- Sterile Surgical Drape Packs
- Sterile Latex Examination Gloves
- Sterile Nitrile Examination Gloves
- Non-Sterile Examination Gloves
- Non-woven Product: Sterile Surgical Drape, Sterile Surgical Gowns, Disposable Facemasks, Caps, Shoe Covers, Isolation Gowns, Coats, Aprons, Dental Bibs, Washing Gloves, Coveralls, Boot Covers, Pillow Cases, Bed Sheets, Sleeve Covers, Under Pads, Patient Gowns, Scrub Suits, Beard Covers, Kimonos, Wipes

**Certification Body**



**Date:** 2020-02-19



**Wenxiang Zhang**

**Business Stream Products**  
**Certification Department**



**Precisely Right.**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Raysen (Tianjin) Healthcare  
Products Co., Ltd.  
No. 3, Huanyuxi Road, Tianyu Techno  
Park, Jinghai District  
301609 TIANJIN  
P.R. CHINA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date March 09, 2020

**Application for** : QMS  
Certificate No. : SX 60143691 Sheet 0001  
Device : Only for QM-System audit  
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the  
new certificate No. SX 60143691 0001  
replacing the previous certificate.

Kind regards

Certification body

Wenxiang Zhang

A handwritten signature in blue ink, appearing to read 'Zhang' with a stylized flourish.

Test sample: no, documentation available

TÜV Rheinland  
LGA Products GmbH

Tillystraße 2  
90431 Nürnberg

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