

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

Doc. 1/1, Rev. 0

**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



TÜVRheinland®
LGA

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

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

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
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