

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



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

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'.

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

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Fax +49 911 655-5226
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Web www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

TRADUÇÃO PT

Certificado

O Organismo the Certificação da
TÜV Rheinland LGA Products GmbH

por meio deste certifica a organização

**Raysen (Tianjin) Healthcare
Products Co., Ltd
3, Huanyuxi Road, Tianyu Technology
Park, Jinghai District
301609 Tianjin
P.R. China**

estabeleceu e aplica um sistema de gestão de qualidade para dispositivos
médicos para o seguinte escopo:

**Fabrico e Distribuição de Dispositivos Médicos
(ver anexo para os produtos incluídos)**

Foi fornecida prova de que os requisitos especificados na

EN ISO 13485: 2016

foram cumpridos. O sistema de gestão da qualidade está sujeito a vigilância anual.

Data Efetiva.:	2020-02-19
No de Registo do Certificado.:	SX 60143691 0001
Foi realizada uma auditoria. Relatório No.	16806293 006
Este Certificado é válido até.:	2022-08-17

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Anexo ao
Certificado**

Registo No.: SX 60143691 0001

Relatório No.: 16806293 006

Organização:

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

Escopo:

Produtos:

- Campos Cirúrgicos Estéreis
- Luvas Estéreis de Exame de Latex
- Luvas Estéreis de Exame de Nitrilo
- Luvas de Exame Não-estéreis
- Produtos TNT: Campos Cirúrgicos Estéreis, Batas Cirúrgicas Estéreis, Máscaras Descartáveis, Barretes, Cobre-sapatos, Batas de proteção, Casacos, Aventais, Babetes Dentários, Luvas laváveis, Fatos de Proteção, Cobre botas, Fronhas, Lençóis, Manguitos, Pensos absorventes, Batas de Visita, Conjunto Túnica e Calça, Proteção de barba, Kimonos e Toalhetes.

Produtos de Fluxo de negócios Departamento de Certificação

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

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No. 3, Huanyuxi Road, Tianyu Technology
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Mail service@de.tuv.com

Data Março 09, 2020

Aplicação para	: QMS
Certificado No.	:SX 60143691 Sheet 0001
Dispositivo	:Apenas para auditoria QM-Sistema
Requisito de teste	:EN ISO 13485:2016

Exmos senhores,

Em anexo, encontre o novo certificado nº SX 60143691 0001,
substituindo o certificado anterior.

Melhores cumprimentos

Corpo de Certificação

Wenxiang Zhang

Amostra de teste: não. documentação disponível

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