

### **EC** Certificate

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

Registration No.: DD 60143692 0001

Report No.: 16806293 006

Manufacturer: Raysen (Tianjin) Healthcare

Products Co., Ltd.

No. 3, Huanyuxi Road, Tianyu Technology

Park, Jinghai District

301609 Tianjin P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60111402 0001

**Expiry Date:** 2021-08-17

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: 2020-02-19

Date: 2020-02-19

TÜV Rheinland LGA Products GmbH - Tillystraße 299 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.

Notified Bo

Wenxiang Zhand



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

Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.:

DD 60143692 0001

Report No.:

16806293 006

Manufacturer:

Raysen (Tianjin) Healthcare

Products Co., Ltd.

No. 3, Huanyuxi Road, Tianyu Technology

Park, Jinghai District 301609 Tianjin

P.R. China

#### Products:

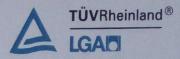
Aspects of Manufacture Concerned with Securing and Maintaining Sterile Conditions:

- -Sterile Nonwoven Surgical Gowns
- -Sterile Nonwoven Surgical Drape
- -Sterile Latex Examination Gloves
- -Sterile Nitrile Examination Gloves
- -Sterile Surgical Drape Packs

Date: 2020-02-19







Contact

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

Date March 09, 2020

# 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

Application for : QMS Produktion, Anhang V MDD

Certificate No. : DD 60143692 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60143692 0001 replacing the previous certificate.

Kind regards

Certification body

Wenxiang Zhang

Test sample: no, documentation available

Tillystraße 2 90431 Nürnberg

TÜV Rheinland LGA Products GmbH

Tel. +49 911 655-5225 Fax +49 911 655-5226 Mail service@de.tuv.com 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



Doc. 1/1, Rev. 0

## 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







## 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 Nürnber Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com





Precisely Right.

Contact

Tel. +49 911 655-5225

Date March 09, 2020

Mail service@de.tuv.com

Business Stream Products
Certification Department

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

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

Tillystraße 2 90431 Nürnberg

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