

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

Notified Body



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 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.



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

Notified Body


Wenxiang Zhang



Business Stream Products
Certification Department



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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 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

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

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

Board of Management

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Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490



由 扫描全能王 扫描创建

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



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>





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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

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

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LGA Products GmbH

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Board of Management

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