

TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

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

Date August 12, 2022

Application for: QMS

Certificate No. : SX 2180661-1

Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate No. SX 2180661-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Wenxiang Zhang
Certification body



TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2180661-1

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

Scope: **Manufacture and Distribution of Product:**
-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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190139285 110
Effective date: 2022-08-18
Expiry date: 2025-08-17
Issue date: 2022-08-12



Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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Contact

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Date August 12, 2022

Application for: Vollst. QMS Annex V MDD
Certificate No.: DD 2180661-1
Requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

A surveillance audit of your quality management system was performed.

The audit team confirmed that your quality management system is applied effectively with respect to the above-mentioned requirements.

This letter confirms that the above-mentioned certificate will remain valid.

Best regards,

Wenxiang Zhang
Certification body



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