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Certificate No. 60151568

Certificate Number: 60151568

Certificate Holder:
Henan Lantian Medical Supplies Co., Ltd.
Dingluan Industrial Park
Dingluan Town
Changyuan County
453400 Henan
China (Mainland)

Scope: Manufacture and Distribution of Disposable Sterile Medical Face Masks, Disposable Sterile Surgical Gowns, Disposable Medical Surgical Drapes, Sterile Drape Packs, Sterile Dressing Packs

Fulfilled Standards: EN ISO 13485:2016

QMS

Quality Management System
EN ISO13485 quality management standard for medical devices and related services

Certificate Type: The European standard EN ISO 13485 specifies requirements for a quality management system when an organization is required to demonstrate its ability to provide medical devices and related services that constantly meet customer requirements and applicable legal requirements.

Competent auditors analyze and evaluate the customer's quality management system. If all applicable requirements are met, its quality management system is certified according to EN ISO 13485.

The customer's quality management system is subject to regular monitoring.

Certified customers may use the test mark in their communication.

Further information on this service can be found here.

Further Information

- Request more information on Henan Lantian Medical Supplies Co., Ltd.
- All certified management systems of Henan Lantian Medical Supplies Co., Ltd.

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Close

Cookies management panel

By allowing these third party services, you accept their cookies and the use of tracking technologies necessary for their proper functioning.

[Privacy policy](#)

Preference for all services

Allow all cookies

Deny all cookies

- [+ APIs](#)

APIs are used to load scripts: geolocation, search engines, translations, ...

- [+ Advertising network](#)

Ad networks can generate revenue by selling advertising space on the site.

- [+ Audience measurement](#)

Audience measurement services are used to generate attendance statistics to improve the site.

- Webtrekk This service can install 7 cookies.

Allow

Deny

- [+ Comments](#)

Comments managers facilitate the filing of comments and fight against spam.

- [+ Other](#)

Services to display web content.

- [+ Social networks](#)

Social networks can improve the usability of the site and help to promote it via the shares.

- [+ Support](#)

Support services allow you to get in touch with the site team and help to improve it.

- [+ Videos](#)

Video sharing services help to add rich media on the site and increase its visibility.

Cookies manager by tarteacitron.js

EC Certificate



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

Registration No.: DD 2181010-1

Manufacturer: Henan Lantian Medical Supplies
Co., Ltd.
Dingluan Industrial Zone,
Changyuan City,
453400 Henan
P.R. China

Products: For the following medical devices the scope covers only the aspects of
manufacture concerned with securing and maintaining sterile conditions:
Disposable Sterile Medical Face Masks, Disposable Sterile Surgical
Gowns, Disposable Medical Surgical Drapes, Sterile Drape Packs, Sterile
Dressing Packs


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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.

Report No.: 244310111-200

Effective date: 2021-02-20

Expiry date: 2024-05-26

Issue date: 2021-02-20



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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 • 51105 Köln

Henan Lantian Medical Supplies
Co., Ltd.
Dingluan Industrial Zone,
Changyuan City,
453400 Henan
P.R. China

Contact

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Mail: service@de.tuv.com

Date February 22, 2021

Application for: Vollst. QMS Produktion, Anhang V MDD

Certificate No.: DD 2181010-1

Requirement : Richtlinie 93/42/EWG

Dear Madame or Sir

Enclosed please find the new certificate No. DD 2181010-1 replacing the previous certificate.

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

Best regards,



Fuxiu Sheng
Certification body

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LGA Products GmbH

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Germany

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