



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

Registration No.: DD 60145760 0001

Report No.: 16806100 007

Manufacturer: XINLE HUABAO MEDICAL
PRODUCTS CO., LTD.
Dongguan, Cheng'an Town
050701 Xinle City, Hebei Province
P.R. China

Products: Medical Devices

(See Attachment for Products included)

Replaces Approval, Registration No.: DD 60110792 0001

Expiry Date: 2024-05-26

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: 2020-01-19

Date: 2020-01-19

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**

**Attachment to
Certificate**

Registration No.: DD 60145760 0001
Report No.: 16806100 007

Manufacturer: XINLE HUABAO MEDICAL
PRODUCTS CO., LTD.
Dongguan, Cheng'an Town
050701 Xinle City, Hebei Province
P.R. China

Products:

- Sterile Non-woven Products (Surgical Gowns, Surgical Drapes, Isolation Gowns, Coveralls, Face Masks)
- Sterile Non-woven and PE Compositated Products (Surgical Gowns, Surgical Drapes, Isolation Gowns, Coveralls)

Date: 2020-01-19

Notified Body





**Business Stream Products
Certification Department**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

XINLE HUABAO MEDICAL
PRODUCTS CO., LTD.
Dongguan, Cheng'an Town
050701 XINLE CITY, HEBEI PROVINCE
P.R. CHINA

Contact

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

Date January 19, 2020

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60145760 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 60145760 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body


Jing Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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90431 Nürnberg

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