

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

Registration No.: DD 60146761 0001

Report No.: 50308314 002

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

Products: Medical Devices

(See attachment for Products included)

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: 2020-04-13

Date: 2020-04-13



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 60146761 0001
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For the Following Medical Devices the Scope Covers the
Aspects of Manufacture concerned with Securing and
Maintaining Sterile Conditions:

- Disposable Surgical Gowns
- Disposable Medical Masks
- Disposable Medical Caps
- Disposable Medical Drapes
- Medical Gauze Sponges
- Medical Cotton Swabs
- Medical Cotton Balls

Date: 2020-04-13

Notified Body


Wenxiang Zhang

Business Stream Products
Certification Department



Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Henan Yatai Medical Supplies
Co., Ltd.
Mancun Industrial Zone, Changyuan C
453400 HENAN
P.R. CHINA

Contact

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

Date April 14, 2020

Application for : **QMS Produktion, Anhang V MDD**
Certificate No. : DD 60146761 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. DD 60146761 0001.

Kind regards

Certification body

Wenxiang Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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