



TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Changzhou Jinlong Medical Plastic Appliance Co., Ltd. Zhenglu Town Changzhou **213111 JIANGSU** P.R. CHINA

Contact

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

Date April 08, 2020

Application for : QMS Produktion, Anhang V MDD

Certificate No.

: DD 60147424 Sheet 0001 : Only for QM-System audit

Device

Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60147424 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

Jason Pan

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** 

Dipl.-Ing. Jörg Mähler, Spokesman

Dipl.-Kfm. Dr. Jörg Schlösser

Chairman of the Supervisory Board

Dipl.-Ing. Ralf Scheller

Nuremberg HRB 26013 VAT No.: DE 811835490



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

Registration No.: DD 60147424 0001

Report No.:

15056348 010

Manufacturer:

Changzhou Jinlong Medical Plastic Appliance Co., Ltd.

Zhenglu Town Changzhou 213111 Jiangsu

P.R. China

**Products:** 

Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60124758 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:

2020-04-07

Date:

2020-04-07

Notified Body

Jason Pan

April 1 june 1 jun

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 60147424 0001

Report No.:

15056348 010

Manufacturer:

Changzhou Jinlong Medical Plastic Appliance Co., Ltd. Zhenglu Town Changzhou 213111 Jiangsu P.R. China

## Products:

- Sterile Syringes for Single Use
- Sterile Infusion Sets for Single Use
- Sterile Intravenous Needles for Single Use
- Sterile Hypodermic Needles for Single Use
- Sterile Blood Transfusion Sets for Single Use
- Disposable Biopsy Forceps

**Notified Body** 

FYNZE FLED

Jason Pan

TÜVRheinland III

Date: 2020-04-07