

**Business Stream Products
Certification Department**



TÜVRheinland®

LGA

Precisely Right.

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
Device : Only for QM-System audit
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

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LGA Products GmbH

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Supervisory Board

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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



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 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

Date: 2020-04-07

Jason Pan
Jason Pan

