

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



**Registration No.:** DD 60149774 0001

**Report No.:** 15079747 011

**Manufacturer:** Changzhou Huankang  
Medical Device Co., Ltd.  
22 Changhe Road, Sanhekou, Zhenglu  
213116 Changzhou, Jiangsu  
P.R. China

**Products:** Disposable Medical Devices  
(see attachment for products and sites included)  
Replaces Approval, Registration No.: DD 60140255 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:** 2020-08-28

**Notified Body**

**Date:** 2020-08-28

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**

Doc. 1/1, Rev.0

**Attachment to  
Certificate**

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**Products:**

Nasal Oxygen Cannulaes, Suction Catheters, Stomach Tubes,  
Feeding Tubes, Suction Connecting Tubes with Yankauer,  
Endotracheal Tubes, Oxygen Masks, Mucus Extractors,  
Disposable Trocars, Disposable Endoscopic Retrieval Bags,  
Disposable Gynecological Kits, Disposable Biopsy Forceps,  
Disposable Veress Needles;

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

Disposable Vaginal Speculums, Disposable Urine Drainage  
Bags, Disposable Colostomy Bags, Nelaton Catheters, Rectal  
Tubes, Disposable Vaginal Irrigation Sets, Medical Brushes,  
Irrigation Syringes, Enema Bags, Vomit Bags, Umbilical Cord  
Clamps, Disposable Waste Liquid Suction Bags

**Notified Body**

**Date:** 2020-08-28

*Jason Pan*  
Jason Pan



**Business Stream Products**  
**Certification Department**



**TÜVRheinland®**

**LGA**

**Precisely Right.**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Changzhou Huankang  
Medical Device Co., Ltd.  
22 Changhe Road, Sanhekou, Zhenglu  
213116 CHANGZHOU, JIANGSU  
P.R. CHINA

Contact

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Date September 04, 2020

**Application for : QMS Produktion, Anhang V MDD**  
Certificate No. : DD 60149774 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 60149774 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

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