

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**

Registration No.: DD 60149774 0001
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Manufacturer: Changzhou Huankang
Medical Device Co., Ltd.
22 Changhe Road, Sanhekou, Zhenglu
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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
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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

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

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

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