TÜVRheinland®

EC Certificate

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

Registration No.: DD 60112728 0001

Report No.: 15095315 001

Manufacturer:
Changzhou ZhongYou Medical
Device Co., Ltd.
Wugang, Zhenglu Town
Changzhou
213115 Jiangsu
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60040100 0001

Expiry Date: 2021-07-28

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.

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland III Zertifizierungsstelle III

X. Ren

Effective Date: 2016-08-08

Date: 2016-08-08

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.

Digitally signed by Potînga Stela
Date: 2019.12.09 13:02:56 EET
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Location: Moldova

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

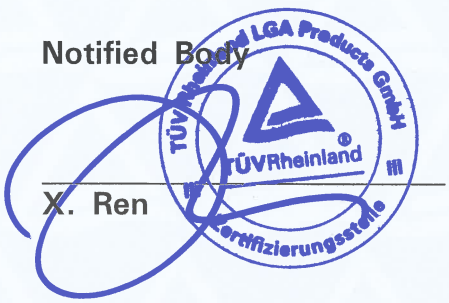
Attachment to Certificate
Registration No.: DD 60112728 0001
Report No.: 15095315 001

Manufacturer:
Changzhou ZhongYou Medical Device Co., Ltd.
Wugang, Zhenglu Town
Changzhou
213115 Jiangsu
China

Products:
- Suction Catheters
- Stomach Tubes
- Feeding Tubes
- Mucus Extractors
- Urinary Catheters (Nelaton Catheters, Tiemann Catheters)
- Oxygen Masks
- Nebulizer Masks

For following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:
- Nasal Oxygen Cannulae
- Disposable Urine Drainage Bags
- Cervical Scrapers
- Medical Brushes
- Rectal Catheters
- Suction Connecting Tubes with Yankauer

Notified Body



Date: 2016-08-08

X. Ren