

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2027449-1

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

Replaces Approval, Registration No.: DD 60112728 0001

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.

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.