

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2183016-1

Manufacturer: Changzhou Medical Appliances General
Factory Co., Ltd.
Hengshanqiao Town, Wujin District,
Changzhou
213119 Jiangsu
P.R. China

Products: Infusion Sets, Transfusion Sets, Syringes for Single Use, Hypodermic
Needles, Scalp Vein Sets, Oxygen Masks, Sterile Nasal Oxygen Tubes,
Nebulizer Masks;

Aspects of manufacture concerned with securing and maintaining sterile
conditions: Sterile Urine Bags, Sterile Latex Examination Gloves, Sterile
Vaginal Speculum

Replaces Approval, Registration No.: DD 60110015 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.