TÜVRheinland

EC Certificate

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

Registration No.: DD 60110015 0001

Report No.: 15085675 001

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

Expiry Date: 2020-10-30

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: 2016-05-30

Date: 2016-05-30

Notified Body

X. Ren

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.