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TÜVRheinland®

EC Certificate

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

Registration No.: DD 2027188-1

Manufacturer: Shandong Wuzhou Medical Equipment Co., Ltd.
Dingtao (Yantai) Industrial Area, Heze, 274100 Shandong,
P.R. China

Products:
- Disposable Syringe with Needles
- Infusion Sets
- Blood Transfusion Sets
- Insulin Syringes
- Hypodermic Needles
- Intravenous Needles
- Sterile Self-destruction Safety Syringes for Single Use
- Safety Blood Collection Needles for Single Use
- Intravenous Infusion Sets with Burette
- Hemodialysis Blood Tubing Sets
- Disposable Dental Needles
- Sterile Lancets for Single Use
- Insulin Pen Needles

Aspects of Manufacture concerned with Securing and Maintaining Sterile Conditions of: Drainage Bags, Vaginal Dilators, Sterile Dental Irrigation Syringes, Sterile Dental Irrigation Needle Tips

Replaces Approval, Registration No.: DD 60150062 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.

Report No.: 16806396.007

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TÜV Rheinland LGA Products GmbH

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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.