

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

Registration No.: DD 60081893 0001

Report No.: 17029214 001

Manufacturer: Shantou Wealy Medical Instrument
Co., Ltd.
North Jinhuan Road
(near of Qishan Mid-school)
Shantou
515064 Guangdong
China

Products: Disposable Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60020792 0001

Expiry Date: 2017-12-12

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: 2012-12-13

Date: 2012-12-13



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60081893 0001
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Manufacturer: Shantou Wealy Medical Instrument
Co., Ltd.
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Shantou
515064 Guangdong
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Products:

- Disposable Syringes (with Needle)
- Disposable Insulin Syringes
- Infusion Sets with Burette (for Children)
- Disposable Scalp Vein Sets
- Disposable Infusion Sets (with Needle)
- Disposable Hypodermic Needles
- Disposable Safety Syringes
- Disposable I.V. Cannulas
- Disposable Tuberculin Syringes
- Disposable Infusion Sets with Precision Filters

**Aspects of manufacture concerned with securing
and maintaining sterile conditions:**

- Disposable Feeding Catheters
- Disposable Vaginal Speculums
- Disposable Irrigation Syringes
- Disposable Suction Connecting Tubes
- Medical Silicone Rubber Tubes
- Disposable Enteral Feeding Syringes

Date: 2012-12-13

Notified Body



X. Ren