

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 2058619-1

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

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 Tuberculin Syringes, Disposable Infusion Sets with Precision Filters, Disposable Insulin Safety Syringes

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

Replaces Approval, Registration No.: DD 60122721 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.: 10918546-100

Effective date: 2021-02-01

Expiry date: 2024-05-26

Issue date: 2021-02-01



Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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