

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

Registration No.: DD 60125955 0001

Report No.: 15049519 006

Manufacturer: Shanghai Dochem
Industries Co., Ltd.
Suite E2014, 2nd Floor
No. 3558 Zhenbei Road, Putuo District
200062 Shanghai
China

Products: Medical Devices
(see attachment for products and site included)
Replaces Approval, Registration No.: DD 60077952 0001

Expiry Date: 2022-07-16

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: 2018-01-04

Date: 2018-01-04

Notified Body



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

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60125955 0001
Report No.: 15049519 006

Manufacturer:

**Shanghai Dochem
Industries Co., Ltd.
Suite E2014, 2nd Floor
No. 3558 Zhenbei Road, Putuo District
200062 Shanghai
China**

Products:

Disposable Syringes, Sterile Dental Needles for Single Use,
Sterile Absorbent Paper Points, Gutta Percha Points,
Synthetic Resin Teeth Series, Dental Cements Series, Dental
Burs, Disposable Dental Suction Tips, Disposable Dental
Syringe Tips, Disposable Dental Saliva Ejectors, Disposable
Dental Prophylaxis Cups, Disposable Dental Prophylaxis Brushes,
Disposable Dental Prophylaxis Angles, Surgical Operational Kits;

Aspects of manufacture concerned with securing and
maintaining sterile condition:

Surgical Gowns, Face Masks, Non-woven Caps, Dental Cotton
Rolls, Gauze Sponges, Cotton Tip Applicators, Non-woven
Sponges, Disposable Oral Cavity Kits and Implements

Site included:

Suite 2701-04, No. 7, Fuli Building, Lane 1306, Jiang Ning
Road, 200060 Shanghai, China

Date: 2018-01-04

Notified Body



X. Ren