

**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

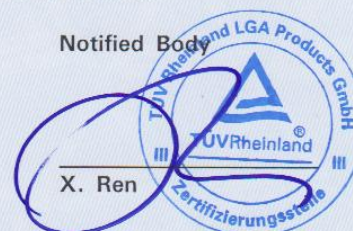
**Products:** Medical Devices  
  
(see attachment for products and site included)  
  
Replaces Approval, Registration No.: DD 60077952 0001

**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



**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**

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**Report No.:** 15049519 006

**Manufacturer:** Shanghai Dochem  
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**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 Prophy Cups, Disposable Dental Prophy Brushes,  
Disposable Dental Prophy 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

