

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

**Registration No.:** DD 60145757 0001

**Report No.:** 15091167 009

**Manufacturer:** GAUKE Healthcare Co., Ltd.  
Chengnan Industrial Park  
Tuanfeng County  
HuangGang  
438800 Hubei  
P.R. China

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: DD 60140361 0001

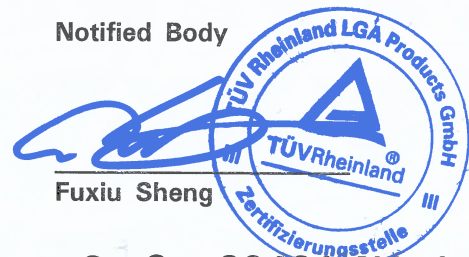
**Expiry Date:** 2024-05-26

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:** 2020-02-24

**Date:** 2020-02-24

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**

**Attachment to  
Certificate**

**Registration No.:** DD 60145757 0001  
**Report No.:** 15091167 009

**Manufacturer:** GAUKE Healthcare Co., Ltd.  
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**Products:**

Medical Gauze Swabs/Lap Sponges/Gauze Balls with  
X-ray Detectable;

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

Medical Gauze Swabs /Gauze Balls, Absorbent Cotton  
Rolls/Cotton Balls/Cotton Pads/Gauzes, Sterile Non-woven  
Sponges/Balls, First Aid Kits, Sterile Bandages, Sterile  
Dressings, Wound Plasters

**Date:** 2020-02-24

**Notified Body**



**Fuxiu Sheng**

