

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

Registration No.: DD 60108339 0001

Report No.: 15091167 001

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

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: DD 60038309 0001

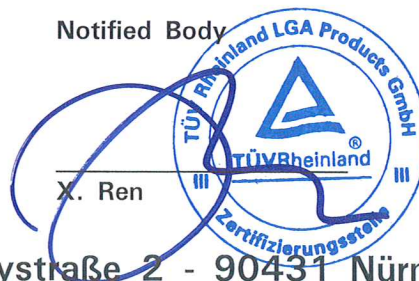
Expiry Date: 2021-03-14

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: 2016-03-15

Date: 2016-03-15

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**

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Manufacturer: GAUKE Healthcare Co., Ltd.
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Products:

- Medical Gauze Swabs with X-ray Detectable
- Medical Lap Sponges with X-ray Detectable
- Medical Gauze Balls with X-ray Detectable
- Sterile Single use Cleansing Products
- Cold Packs

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Absorbent Cotton Rolls
- Absorbent Cotton Balls
- Absorbent Cotton Pads
- Absorbent Gauzes
- Sterile Non-woven Sponges/Balls
- First Aid Kits
- Sterile Bandages
- Sterile Dressings
- Wound Plaster

Site included:

Suite 105, Huixianlou, HuiFeng Enterprise Park, GuTianErlu,
ChangFeng Lu, Wuhan, Hubei Province 430035, China

Date: 2016-03-15

Notified Body



X. Ren