

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

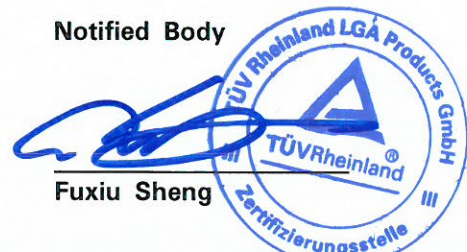
Expiry Date: 2024-05-26

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

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

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 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

Notified Body

Date: 2020-02-24



Fuxiu Sheng



The stamp is circular with a blue border. Inside the border, the text 'TÜV Rheinland LGA Products GmbH' is written at the top and 'Zertifizierungsstelle' at the bottom. In the center, there is a stylized blue triangle logo with the text 'TÜVRheinland' below it.