

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60138384 0001

Report No.: 15095988 007

Manufacturer: Jiangsu BANA Medical Technology
Co., Ltd.
No. 28-3 Guihua Road
Zhonglou Economic Development Zone
Changzhou
213013 Jiangsu
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60129380 0001

Expiry Date: 2021-09-07

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-04-25

Date: 2019-04-25

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.: HD 60138384 0001
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Manufacturer: Jiangsu BANA Medical Technology
Co., Ltd.
No. 28-3 Guihua Road
Zhonglou Economic Development Zone
Changzhou
213013 Jiangsu
China

Products:

- Hernia Patches
- Disposable Prepuce Cutter Staplers
- Hernia Staplers
- Disposable Endoscopic Ligating Loops
- Disposable Endoscopic Graspers
- Disposable Endoscopic Scissors
- Disposable Endoscopic Dissectors
- Disposable Suction and Irrigation Tubes
- Biopsy Forceps
- Disposable Endoscopic Retrieval Bags
- Disposable Trocars
- Disposable Clip Appliers
- Disposable Veress Needles
- Non-sterile Metallic Bone Plates
- Non-sterile Metallic Bone Screws
- Spinal Internal Fixation
- Non-sterile Metallic Intramedullary Femur Nails
- Non-sterile Metallic Intramedullary Tibia Nails
- Non-sterile Metallic Intramedullary Humerus Nails

Date: 2019-04-25

Notified Body



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Dilators

Date: 2019-04-25

Notified Body

