

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

Registration No.: HD 60121244 0001

Report No.: 16801770 009

Manufacturer: B.J.ZH.F.PANTHER
MEDICAL EQUIPMENT CO., LTD
Floor 3, Building 1
28 Huoju Street, Changping Science
and Technology Park
Changping District
102200 Beijing
China

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60116780 0001

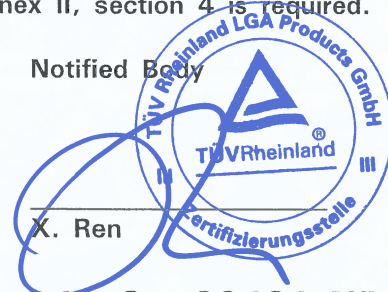
Expiry Date: 2022-11-13

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: 2017-11-14

Date: 2017-11-14

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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Products:

Surgical Staplers, Staples, Trocars, Dilators with Light Source, Endo Stapler Introducers, Accessory Kits for Anorectal Surgery, Disposable Surgical Trocar with Cannula, Disposable Suction Irrigation Set, Disposable Lap Bag, Disposable Veress Needle, Implantable Ligating Clips, Disposable Hand Assist Tunnels and Disposable Purse-String Instruments, Fixation Device with Titanium Tacks;

Aspects of manufacture concerned with securing and maintaining sterile conditions of Sterile Skin Staple Removers

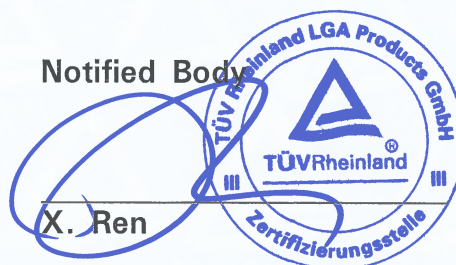
Sites included:

West side No.2, White Bridge industrial Area, Jinzhan Street, Chaoyang District, 100018 Beijing, China

28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China

Date: 2017-11-14

Notified Body



X. Ren