

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

**Registration No.:** HD 60149060 0001

**Report No.:** 16801770 018

**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  
P.R. China

**Products:** Medical Devices

(See Attachment for Products and Sites included)

Replaces Approval, Registration No.: HD 60121244 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:** 2020-04-29

**Date:** 2020-04-29

Notified Body

Wenxiang Zhang



**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 60149060 0001  
**Report No.:** 16801770 018

**Manufacturer:** **B.J.ZH.F.PANTHER**  
**MEDICAL EQUIPMENT CO., LTD**  
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**and Technology Park**  
**Changping District**  
**102200 Beijing**  
**P.R. China**

**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 Sets, Disposable Lap Bags, Disposable Veress Needles, 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, Sterile Surgical Face Masks, Sterile Medical Face Masks, Sterile Surgical Gowns and Sterile Medical Isolation Gowns

**Sites included:**

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

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

**Date:** 2020-04-29

**Notified Body**

**Wenxiang Zhang**



**Business Stream Products**  
Certification Department



Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

B.J.ZH.F.PANTHER  
MEDICAL EQUIPMENT CO., LTD  
Floor 3, Building 1  
and Technology Park  
Changping District  
102200 BEIJING  
P.R. CHINA

Contact

Tel. +49 911 655-5225  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)

Date April 29, 2020

**Application for** : Vollst. QMS, Anhang II MDD  
Certificate No. : HD 60149060 Sheet 0001  
Device : Only for QM-System audit  
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. HD 60149060 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Wenxiang Zhang

A blue handwritten signature of Wenxiang Zhang.

Test sample: no, documentation available

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LGA Products GmbH

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90431 Nürnberg

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