

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**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

has established and applies a quality management system for medical devices  
for the following scope:

(See attachment for Products and Additional Sites included)

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-04-29  
Certificate Registration No.: SX 60149059 0001  
An audit was performed. Report No.: 16801770 018  
This Certificate is valid until: 2020-11-13

Certification Body



Date 2020-04-29



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel: +49 221 806-1371 Fax: +49 221 806-3635 e-mail: cert-safety@de.tuv.com http://www.tuv.com/safety



Doc: 1/4, Rev. 0

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60149059 0001  
**Report No.:** 16801770 018

**Organization:**

**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

**Scope:**

Design and Development, Manufacture and Distribution of Surgical Staplers, Staples, Trocars, Dilators with Light Source, Thoracic and General Surgical Instruments, Endo Stapler Introducers, Accessory Kits for Anorectal Surgery, Sterile Skin Staple Removers, Disposable Surgical Trocar with Cannula, Disposable Suction Irrigation Sets, Disposable Lap Bags, Disposable Veress Needles, Implantable Ligating Clips, Clip Applicators, Disposable Hand Assist Tunnels, Disposable Purse-String Instruments, Clip Removers, Fixation Device with Titanium Tacks, Disposable Powered Articulating Endoscopic Cutter Staplers, Ultrasonic Activated Scalpel Systems, Ultrasonic Disposable Shears, Sterile and Non-sterile Surgical Face Masks, Sterile and Non-sterile Medical Face Masks, Sterile and Non-sterile Surgical Gowns and Sterile and Non-sterile Medical Isolation Gowns

**Certification Body**



**Date:** 2020-04-29



**Wenxiang Zhang**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 2/4, Rev: 0

**Attachment to  
Certificate**

**Registration No.: SX 60149059 0001**  
**Report No.: 16801770 018**

**Organization:** **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

**Scope:**

**Sites included:**

West Side No.2, White Bridge industrial Area, Jinzhan Street,  
Chaoyang District, 100016 Beijing, P. R. China

Manufacture of Surgical Staplers, Staples, Trocars,  
Dilator with Light Source, Thoracic and General Surgical  
Instruments, Endo Stapler Introducers, Accessory Kits for  
Anorectal Surgery, Sterile Skin Staple Removers, Disposable  
Surgical Trocar with Cannula, Disposable Suction Irrigation  
Sets, Disposable Lap Bags, Disposable Veress Needles,  
Implantable Ligating Clips, Clip Applicators, Disposable Hand  
Assist Tunnels, Disposable Purse-String Instruments and Clip  
Clip Removers, Fixation Device with Titanium Tacks,  
Disposable Powered Articulating Endoscopic Cutter Staplers,  
Ultrasonic Activated Scalpel Systems, Ultrasonic Disposable  
Shears, Sterile and Non-sterile Surgical Face Masks,  
Sterile and Non-sterile Medical Face Masks, Sterile and  
Non-sterile Surgical Gowns, Sterile and Non-sterile  
Medical Isolation Gowns

**Certification Body**

**DAkkS**

Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02

**Date: 2020-04-29**



**Wenxiang Zhang**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60149059 0001  
**Report No.:** 16801770 018

**Organization:**

**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

**Scope:**

**Sites included:**

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

Design and Development, Manufacture and Distribution of  
Surgical Staplers, Staples, Trocars, Dilator with  
Light Source, Thoracic and General Surgical Instruments,  
Endo Stapler Introducers, Accessory Kits for  
Anorectal Surgery, Sterile Skin Staple Removers, Disposable  
Surgical Trocar with Cannula, Disposable Suction Irrigation  
Sets, Disposable Lap Bags, Disposable Veress Needles,  
Implantable Ligating Clips, Clip Applicators, Disposable Hand  
Assist Tunnels, Disposable Purse-String Instruments and Clip  
Clip Removers, Fixation Device with Titanium Tacks,  
Disposable Powered Articulating Endoscopic Cutter Staplers,  
Ultrasonic Activated Scalpel Systems, Ultrasonic Disposable  
Shears

**Certification Body**



Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02

**Date:** 2020-04-29



**Wenxiang Zhang**



TÜVRheinland

Doc. 4/4, Rev. 0

TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg

Attachment to  
Certificate

Registration No.: SX 60149059 0001  
Report No.: 16801770 018

Organization: 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

Scope:

Sites included:

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

Design and Development, Distribution of Sterile and  
Non-sterile Surgical Face Masks, Sterile and Non-sterile  
Medical Face Masks, Sterile and Non-sterile Surgical Gowns,  
and Sterile and Non-sterile Medical Isolation Gowns

Certification Body

DAKKS

Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02

Date: 2020-04-29



Wenxiang Zhang

**Business Stream Products  
Certification Department**

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



**TÜVRheinland®**  
**LGA**

Precisely Right.

Contact

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

Date April 29, 2020

**Application for** : QMS  
**Certificate No.** : SX 60149059 Sheet 0001  
**Device** : Only for QM-System audit  
**Test requirement** : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the new certificate No. SX 60149059 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

Test sample: no, documentation available

TÜV Rheinland  
LGA Products GmbH

Tillystraße 2  
90431 Nürnberg

Tel. +49 911 655-5225  
Fax +49 911 655-5226  
Mail [service@de.tuv.com](mailto:service@de.tuv.com)  
Web [www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schösser

Chairman of the  
Supervisory Board

Dipl.-Ing.  
Ralf Scheller

Nürnberg HRB 26013  
VAT No. : DE 811835400