

EC Certificate

Full Quality Assurance System MDD Annex II excl. 4

Registration No.: HD 2185282-1

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: 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 Fixation Device with Titanium Tacks, Endoscopic Motorized Cutting Staplers for Single-use, Ultrasonic Surgical System Generators, Soft-tissue Ultrasonic Surgical System Holders/Tips for Single-use.

For the Following Medical Devices the Scope covers the Aspects of Manufacture concerned with Securing and Maintaining Sterile Conditions: Sterile Skin Staple Removers, Sterile Surgical Face Masks, Sterile Medical Face Masks, Sterile Surgical Gowns and Sterile Medical Isolation Gowns

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.

Report No.: 16801770 017

Effective date: 2021-01-12

Expiry date: 2024-05-26

Issue date: 2021-01-12



Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

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MDD Annex II excl. 4**

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Floor 3, Building 1, 28 Huoju Street, Changping Science
and Technology Park, Changping District, 102200 Beijing,
P.R. China

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No.	Location	Product groups manufactured
/01	B.J.ZH.F.Panther Medical Equipment Co., Ltd. West side No.2, White Bridge Industrial Area, Jinzhan Street, Chaoyang District, 100018 Beijing, P.R. China	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 Fixation Device with Titanium Tacks, Endoscopic Motorized Cutting Staplers for Single-use, Ultrasonic Surgical System Generators, Soft-tissue Ultrasonic Surgical System Holders/Tips for Single-use. For the Following Medical Devices the Scope covers the Aspects of Manufacture concerned with Securing and Maintaining Sterile Conditions: Sterile Skin Staple Removers, Sterile Surgical Face Masks, Sterile Medical Face Masks, Sterile Surgical Gowns and Sterile Medical Isolation Gowns

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P.R. China

/02 B.J.ZH.F.Panther Medical Equipment
Co., Ltd.
28 Huoju Street, Changping Science
and Technology Park, Changping
District, 102200 Beijing,
P.R. China

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 Fixation Device with
Titanium Tacks, Endoscopic Motorized Cutting
Staplers for Single-use, Ultrasonic Surgical
System Generators, Soft-tissue Ultrasonic
Surgical System Holders/Tips for Single-use.
For the Following Medical Devices the Scope
covers the Aspects of Manufacture concerned
with Securing and Maintaining Sterile
Conditions: Sterile Skin Staple Removers,
Sterile Surgical Face Masks, Sterile Medical
Face Masks, Sterile Surgical Gowns and
Sterile Medical Isolation Gowns

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Floor 3, Building 1, 28 Huoju Street, Changping Science
and Technology Park, Changping District, 102200 Beijing,
P.R. China

/03 B.J.ZH.F.Panther Medical Equipment
Co., Ltd.
No. 8 Shangcheng Road, Beiqijia,
Changping District, 102209 Beijing,
P.R. China

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 Fixation Device with
Titanium Tacks, Endoscopic Motorized Cutting
Staplers for Single-use, Ultrasonic Surgical
System Generators, Soft-tissue Ultrasonic
Surgical System Holders/Tips for Single-use.
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TÜV Rheinland LGA Products GmbH • 51105 Köln

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Floor 3, Building 1, 28 Huoju Street,
Changping Science and Technology Park, Changping District,
102200 Beijing, P.R. China

Contact

Tel. +49 911 655-5225
Mail: service@de.tuv.com

Date January 13, 2021

Application for: Full Quality Assurance System

Certificate No. : HD 2185282-1

Requirement : MDD Annex II excl. 4

Dear Madam or Sir,

Enclosed please find the new certificate No. HD 2185282-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,


Jing Zhang
Certification body

TÜV Rheinland
LGA Products GmbH

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51105 Köln
Germany

Headquarter

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90431 Nuremberg

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