

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2185282-1

Certificate Holder: 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, Dilator with Light Source,
Thoracic and General Surgical Instruments, Endo Stapler
Introducers, Accessory Kits for Anorectal Surgery, Sterile Skin
Staple Removers, Disposable Lap Bags, Implantable Ligating
Clips, Clip Applicators, Disposable Hand Assist Tunnels, Clip
Removers, 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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 190149708-110

Effective date: 2023-11-14

Expiry date: 2026-11-13

Issue date: 2023-11-10

Replaces certificate SX 2185282-1 issued 2020-11-14

This certificate can be validated on <https://www.certipedia.com>



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

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o 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	Aspects related to Design and Development, Manufacturing and Distribution
/02	c/o 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	Aspects related to Packing and Warehousing
/03	c/o B.J.ZH.F.Panther Medical Equipment Co., Ltd. No. 8 Shangcheng Road, Beiqijia, Changping District 102209 Beijing P.R. China	Aspects related to Design and Development, Manufacturing and Distribution

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