

Certificate

Quality Management System EN ISO 13485:2016

Registration No.:

SX 2090547-1

Organization:

Changzhou Tongchuang Medical Instrument Technology Co., Ltd. Building A1, Hutang Science and

Technology Industrial Park, Hutang Town,

Wujin District, Changzhou,

213161 Jiangsu P.R. China

Scope:

Design and Development, Manufacture and Distribution of Disposable Circular Staplers, Disposable PPH Staplers, Disposable Linear Staplers and Cartridges, Disposable Linear Cutter Staplers and Cartridges, Disposable Skin Staplers, Disposable Cytology Brushes, Disposable Biopsy Forceps, Disposable Grasping Forceps, Disposable Endo Cutter and Cartridges, Disposable Laparoscopic Trocar Kits, Disposable Circumcision Staplers, Disposable Anorectal Ligation Devices and Cartridges, Disposable Incision Protectors, Disposable Retrieval Bags, Disposable Anoscope

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.: 244435714-200 Effective date: 2022-10-24 Expiry date: 2023-12-11

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

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