

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2181243-1

Organization: Changzhou Health Microport Medical Device Co.,Ltd
No. 11 Tuanjie Road, Tianning District,
Changzhou,
213018 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of Hemorrhoidal Multi-Band Ligators with Anoscope, Ligatures Endoscopic Loops, Disposable Injection Needles, Non-vascular Ni-Ti Alloy Self-expanding Stent System, Disposable Balloon Dilatation Catheters, Disposable Biopsy Forceps, Disposable Cytology Brushes, Multi-chamber Polyp Traps, Biopsy Valves, Disposable Grasping Forceps, Bougie Dilator Sets, Guide Wires, Disposable Circular Staplers, Disposable Circular Staplers for Haemorrhoids, Disposable Linear Staplers, Disposable Linear Cutter Staplers, Disposable Curved Cutter Staplers, Disposable Skin Staplers, Disposable Reloads of Endoscopic Linear Cutter Staplers, Disposable Endoscopic Linear Cutter Staplers, Disposable Polyp Snares, Cleaning Brushes, Bite Blocks

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.

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