

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60147762 0001

Report No.: 15096067 006

Manufacturer: Changzhou Health Microport
Medical Device Co., Ltd.
Heng'an Road 8, Zhenglu
Heping Industrial Park, Tianning
Changzhou
213114 Jiangsu
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60115193 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2021-04-14

Date: 2021-04-14

Notified Body

Jason Pan



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60147762 0001
Report No.: 15096067 006

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Medical Device Co., Ltd.
Heng'an Road 8, Zhenglu
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Products:

Disposable Circular Staplers, Disposable Circular Staplers for Haemorrhoids, Disposable Linear Staplers, Disposable Linear Cutter Staplers, Disposable Curved Cutter Staplers, Disposable Reloads of Endoscopic Linear Cutter Staplers, Disposable Endoscopic Linear Cutter Staplers, Disposable Polyp Snares, Non-vascular Ni-Ti Alloy Self-expanding Stent System; Hemorrhoidal Multi-Band Ligators with Anoscope, Ligatures Endoscopic Loops, Disposable Injection Needles, Disposable Balloon Dilatation Catheters, Disposable Biopsy Forceps, Disposable Cytology Brushes, Disposable Grasping Forceps, Bougie Dilator Sets, Guide Wires, Disposable Skin Staplers;

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Multi-chamber Polyp Traps, Biopsy Valves

Date: 2021-04-14

Notified Body

Jason Pan

