

EC Certificate



Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 2064540-1

Manufacturer: Changzhou Ankang Medical
Instruments Co., Ltd.
A4 Standard Workshop,
Hutang Science & Technology Industrial
Park, Hutang Town, Wujin District,
Changzhou
213164 Jiangsu
P.R. China

Products: Disposable Prolapse Hemorrhoids Staplers, Disposable Circular Staplers,
Disposable Liner Cutter Staplers, Disposable Liner Staplers, Disposable
Curved Cutter Staplers, Disposable Purse String Staplers, Disposable
Endoscopic Linear Cutters Staplers, Disposable Skin Staplers, Disposable
Incision/Wound Protectors, Disposable Endo Bags, Disposable
Laparoscopic Trocars, Cartridges of Disposable Endoscopic Linear Cutter
Staplers, Cartridges of Disposable Linear Staplers, Cartridges of
Disposable Linear Cutter Staplers, Cartridges of Disposable Curved Cutter
Staplers

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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.

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Fuxiu Sheng
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.

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