EC Certificate

TÜVRheinland®

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

Registration No.:	HD 2090547-1
Manufacturer:	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
Products:	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 Ophthalmic Surgical Knives, Disposable Laparoscopic Trocar Kits, Disposable Circumcision Staplers, Disposable Anorectal Ligation Devices and Cartridges, Disposable Incision Protectors, Disposable Retrieval Bags; Aspects of manufacture concerned with securing and maintaining sterile conditions of Disposable Anoscope

Digitally signed by Jighili Tatiana
Date: 2022.11.25 16:42:56 EET
Reason: MoldSign Signature
Location: Moldova

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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TÜV Rheinland LGA Products GmbH
TUVRheinland®
Zertifizierungsstelle

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