TÜVRheinland®

EC Certificate

Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V

Registration No.: DD 2180661-1

Manufacturer: Raysen (Tianjin) Healthcare Products Co., Ltd.
No.3, Huanyuxi Road, Tianyu Technology Park, Jinghai District,
301609 Tianjin, P.R. China

Products: Aspects of manufacture concerned with securing and maintaining sterile conditions:
- Sterile Nonwoven Surgical Gowns
- Sterile Nonwoven Surgical Drapes
- Sterile Latex Examination Gloves
- Sterile Nitrile Examination Gloves
- Sterile Surgical Drape Packs
- Disposable Medical Face Masks
- Disposable Surgical Face Masks
- Disposable Medical Protective Coveralls

Replaces Approval, Registration No.: DD 60147936 0001

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

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TÜV Rheinland LGA Products GmbH

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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.