

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60149331 0001

Report No.: 15096238 004

Manufacturer: Suzhou Kyuan Medical Apparatus
Co., Ltd.
Beiqiao Town
Suzhou City
215144 Jiangsu
P.R. China

Products:

- Sterile Surgical Blades
- Sterile Disposable Scalpels
- Sterile Microsurgical Knives
- Disposable Blood Lancets
- Disposable Safety Lancets

Replaces Approval, Registration No.: DD 60126942 0001

Expiry Date: 2023-02-23

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.

Effective Date: 2021-04-09

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Notified Body

Herbert Zhong



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.