

**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

**Date:** 2021-04-09

**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.