

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60131226 0001

Report No.: 15078953 004

Manufacturer: Jiangsu Ate Medical Technology
Co., Ltd.
No. 8, Lanxiang Road
Wujin Economic Development Zone
213161 Jiangsu
China

Products: Disposable Injection Needles, Disposable Grasping Forceps,
Disposable Biopsy Forceps, Disposable Spray Pipes,
Disposable Hemostatic Clips, Disposable Polypectomy Snares

Replaces Approval, Registration No.: HD 60109072 0001

Expiry Date: 2023-04-13

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.

Effective Date: 2018-07-27

Date: 2018-07-27

Notified Body



X. Ren

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.

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2069530-1

Organization: Jiangsu Ate Medical Technology
Co., Ltd.
No.8, Lanxiang Road,
Wujin Economic Development Zone,
213161 Jiangsu
P.R. China

Scope: Design and Development, Manufacture and Distribution of Disposable
Injection Needles, Disposable Grasping Forceps, Disposable Biopsy
Forceps, Disposable Spray Pipes, Disposable Hemostatic Clips,
Disposable Polypectomy Snares

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244291373-200
Effective date: 2021-04-19
Expiry date: 2024-04-13
Issue date: 2021-04-19



A blue ink signature is written over a circular seal. The seal contains the TÜV Rheinland logo and the text 'TÜV Rheinland LGA Products GmbH', 'TÜVRheinland', and 'Zertifizierungsstelle'.
Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
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