TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices for the following 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

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-07-27
Certificate Registration No.:	SX 60131227 0001
An audit was performed. Report No.:	15078953 004
This Certificate is valid until:	2021-04-13

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-07-27

X. Ren

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