

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Elite Medtek (Jiangsu) Co., Ltd.
28#, Xiahe Rd., Yaoguan Town
Qianjia Industrial Park, Wujin District
Changzhou City
213102 Jiangsu
China

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

Manufacture and Distribution of Medical Devices
(see attachment for products included)

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: 2018-12-03
Certificate Registration No.: SX 60133521 0001
An audit was performed. Report No.: 15085655 004
This Certificate is valid until: 2021-10-27

Certification Body



Date 2018-12-03



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60133521 0001
Report No.: 15085655 004

Organization: Elite Medtek (Jiangsu) Co., Ltd.
28#, Xiahe Rd., Yaoguan Town
Qianjia Industrial Park, Wujin District
Changzhou City
213102 Jiangsu
China

Scope:

Products:

- Y-Connector Sets for single use
- Angiography Syringes for single use
- Pressure Extending Tubings for single use
- Manifolds for single use
- Radial Artery Tourniquets for single use
- Inflation Devices for single use
- Disposable Balloon Inflation Devices

Certification Body



Date: 2018-12-03





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

Registration No.: DD 60122761 0001

Report No.: 15085655 003

Manufacturer: Elite Medtek (Jiangsu) Co., Ltd.
28#, Xiahe Rd., Yaoguan Town
Qianjia Industrial Park, Wujin District
Changzhou City
213102 Jiangsu
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60104633 0001

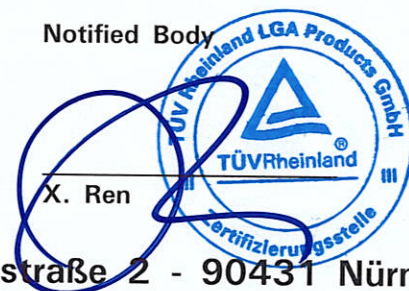
Expiry Date: 2020-10-27

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: 2017-11-27

Date: 2017-11-27

Notified Body



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.

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: DD 60122761 0001
Report No.: 15085655 003

Manufacturer: Elite Medtek (Jiangsu) Co., Ltd.
28#, Xiahe Rd., Yaoguan Town
Qianjia Industrial Park, Wujin District
Changzhou City
213102 Jiangsu
China

Products:

- Y-Connector Sets for single use
- Angiography Syringes for single use
- Pressure Extending Tubings for single use
- Manifolds for single use

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Radial Artery Tourniquets for single use
- Inflation Devices for single use
- Disposable Balloon Inflation Devices

Date: 2017-11-27

Notified Body

