



产品 Products

现有产品：球囊加压装置、桡动脉止血器、Y阀、三通、压力延长管、环柄注射器、导管鞘
Production line: inflation device, radial artery tourniquet, Y connector set, Manifolds, Extending tubing, Angiography control syringe, and introducer sheath set.

压力泵 Inflation Device



- ◆ Quick trigger release to increase patient safety
- ◆ Ergonomic grip design fits comfortably in either hand
- ◆ Stable performance and easy manipulation
- ◆ High resolution display to enhance visibility of digital figures
- ◆ Automatic timer and intelligent memory to record and recall prior inflation information
- ◆ Stable performance and easy manipulation

颜色可选



Y型连接器组件 Y-connector set



- ◆ One handed manipulation to minimize blood loss rapidly and simply
- ◆ Diverse specification for broad choices
- ◆ Large size lumen to offer smooth passage for devices and fluid

多联三通 Manifolds



- ◆ Variety specifications for broad selection
- ◆ Low-torque, easy-to-turn handles to reduce hand fatigue

压力延长管 Pressure extending tubing



- ◆ Clear PVC materials improving high clarity
- ◆ Braided reinforced wires, rating at 1200PSI
- ◆ Variety band length for broad selection

环柄注射器 Angiography Syringe



- ◆ Clear and transparent barrel enables good clinical observation
- ◆ Silent rubber plug creates a unique smooth feeling during injection with less resistance
- ◆ Rotating and fixed male luer allows for flexibility and stability in connection
- ◆ 0.5ml safety fluid space aims to minimize the potential of air bubbles introduced into catheter

桡动脉止血器 Radial artery tourniquet



- ◆ High transparent materials providing easy monitoring of access site
- ◆ Good flexibility and patient comfort
- ◆ Variety band length for broad selection

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

Registration No.: DD 60147785 0001

Report No.: 15085655 008

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

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60122761 0001

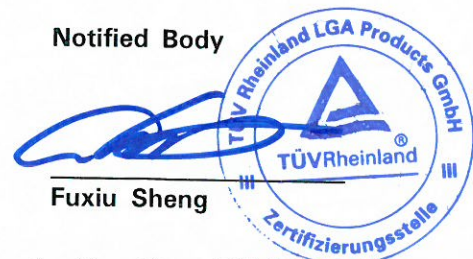
Expiry Date: 2024-05-26

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: 2020-09-08

Date: 2020-09-08

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 60147785 0001
Report No.: 15085655 008

Manufacturer: Elite Medtek (Jiangsu) Co., Ltd.
28#, Xiahe Rd., Yaoguan Town
Qianjia Industrial Park, Wujin District
Changzhou City
213102 Jiangsu
P.R. 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: 2020-09-08

Notified Body



Fuxiu Sheng



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



Allen Chen
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