

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Zhejiang Sujia  
Medical Device Co., Ltd.  
No. 168, Zhenxing Road, Jiaxing  
Zhejiang 314001  
China**

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

**Design and Development, Manufacture and  
Distribution of Medical Devices  
(see attachment for products included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012  
EN ISO 13485:2012/AC:2012**

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

Effective Date: 2016-05-13  
Certificate Registration No.: SX 60109229 0001  
An audit was performed. Report No.: 15067470 003  
This Certificate is valid until: 2019-03-02

Certification Body



Date 2016-05-13

X. Ren

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

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

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

**Attachment to  
Certificate**

**Registration No.:** SX 60109229 0001  
**Report No.:** 15067470 003

**Organization:** Zhejiang Sujia  
Medical Device Co., Ltd.  
No. 168, Zhenxing Road, Jiaxing  
Zhejiang 314001  
China

**Scope:**

**Products:**

- Epidural Anaesthesia Kits
- Analgesia Infusion Pumps
- Rigid Endoscopes
- Tracheal Tubes
- Laryngeal Mask Airways
- Steel-Reinforced Tracheal Tubes
- 3-Way Stopcocks
- Heparin Caps
- Tracheostomy Tubes
- Extension Tubes
- I.V. Catheters
- Mucus Extractors (Suction Tubes)
- Umbilical Cord Clamps
- Urine Collection Bags
- Dressing Kits  
(Disposable General Anaesthesia Dressing Kits,  
Disposable Gastroscope Dressing Kits,  
Disposable Urethral Catheter Dressing Kits,  
Disposable Mucus Extractor Dressing Kits)

**Certification Body**



**Date:** 2016-05-13

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

**Attachment to  
Certificate**

**Registration No.:** SX 60109229 0001  
**Report No.:** 15067470 003

**Organization:** Zhejiang Sujia  
Medical Device Co., Ltd.  
No. 168, Zhenxing Road, Jiaxing  
Zhejiang 314001  
China

**Scope:**

**Products:**

- Disposable Pulse Oximeter Probes
- Peripheral Nerve Plexus Stimulators
- Disposable Peripheral Nerve Plexus Stimulator Kits
- Disposable Blood-Pressure Transducers
- Anesthesia Puncture Kits
- Central Venous Catheter Puncture Kits
- Electronic Analgesia Infusion Pumps
- Respiration Pipes
- Flexible Biopsy Forceps
- Airways
- Anesthesia Gas Absorbers
- Post Partum Blood Coagulation Utensils
- Medical Brushes (Wipers)
- Carbon Dioxide Absorbents (Soda Lime, Calcium Lime)

**Certification Body**



**Date:** 2016-05-13



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

**Registration No.:** HD 60092394 0001

**Report No.:** 15067470 001

**Manufacturer:** Zhejiang Sujia  
Medical Device Co., Ltd.  
No. 168, Zhenxing Road, Jiaxing  
Zhejiang 314001  
China

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: HD 60024385 0001

**Expiry Date:** 2019-03-02

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:** 2014-03-03

**Date:** 2014-03-03



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.

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

**Attachment to  
Certificate**

**Registration No.:** HD 60092394 0001  
**Report No.:** 15067470 001

**Manufacturer:** Zhejiang Sujia  
Medical Device Co., Ltd.  
No. 168, Zhenxing Road, Jiaxing  
Zhejiang 314001  
China

**Products:**

- Epidural Anaesthesia Kits
- Analgesia Infusion Pumps

**Date:** 2014-03-03



**Notified Body**

**Ren**

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

**Registration No.:** DD 60092395 0001

**Report No.:** 15067470 001

**Manufacturer:** Zhejiang Sujia  
Medical Device Co., Ltd.  
No. 168, Zhenxing Road, Jiaxing  
Zhejiang 314001  
China

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: DD 60024386 0001

**Expiry Date:** 2019-03-02

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:** 2014-03-03

**Date:** 2014-03-03



**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.:** DD 60092395 0001  
**Report No.:** 15067470 001

**Manufacturer:** Zhejiang Sujia  
Medical Device Co., Ltd.  
No. 168, Zhenxing Road, Jiaxing  
Zhejiang 314001  
China

**Products:**

- Rigid Endoscopes
- Tracheal Tubes
- Laryngeal Mask Airways
- Steel-Reinforced Tracheal Tubes
- 3-Way Stopcocks
- Heparin Caps
- Tracheostomy Tubes
- Extension Tubes
- I.V. Catheters

For the following medical devices the scope covers only the aspects of manufacture concerned securing and maintaining sterile conditions:

- Mucus Extractors (Suction Tubes)
- Umbilical Cord Clamps
- Dressing Kits
- Urine Collection Bags

**Date:** 2014-03-03

