

Certificate

The Certification Body of
TÜV Rheinland Product Safety 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 the following scope:

**Design and Development, Manufacture and Distribution of
Medical Devices**
Products: see attachment
Sterilization Site and Method: see attachment

Proof has been furnished that the requirements specified in

EN ISO 9001:2000

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

Certificate Registration No.: SY 60024387 0001

An audit was performed. Report No.: 15030316 001

This Certificate is valid until: 14.11.2010

Certification Body

Cologne, 03.03.2009



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln

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

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: **SY 60024387 0001**
Report No.: **15030316 001**

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

Scope:

Products:
- Disposable Medical Products
- Rigid Endoscopes and Accessories

Sterilization Site:
Zhejiang Sujia Medical Device Co., Ltd.
No.168, Zhenxing Rd., Jiaxing,
Zhejiang 314001, P.R.China

Sterilization Method:
E.T.O. Sterilization

Cologne, 03.03.2009



TÜV Rheinland / CCIC (Qingdao)

6F, No.2 Bldg., No.175 Zhuzhou Rd., Qingdao 266101, P.R. China

C E R T I F I C A T E

for a

Quality Management System

according to

EN ISO 13485:2003 + AC:2007

TÜV Rheinland / CCIC (Qingdao) hereby certifies that the

Manufacturer: Zhejiang Sujia Medical Device
Co., Ltd.
No.168,Zhenxing Rd.
Jiaxing, Zhejiang 314001
P.R. China

has established and maintains a quality management system. Conformance with the requirements of the standards has been audited. The organization is subject to a yearly surveillance audit.

Registration No.: SY 50148851 0001

Report No.: 15030316 001

Date of expiry: 02.03.2014

Scope: refer to Attachment

Qingdao, 03.03.2009



TÜV Rheinland / CCIC (Qingdao)

6F, No.2 Bldg., No.175 Zhuzhou Rd., Qingdao
266101, P.R. China

Attachment to

Registration No.: SY 50148851 0001
Report No.: 15030316 001

Manufacturer: Zhejiang Sujia Medical Device
Co., Ltd.
No.168,Zhenxing Rd.
Jiaxing, Zhejiang 314001
P.R. China

Scope: Design and Development, Manufacture and Distribution of
Disposable Medical Products, Rigid Endoscopes and
Accessories

Sterilization Site:
Zhejiang Sujia Medical Device Co., Ltd.
No.168, Zhenxing Rd., Jiaxing, Zhejiang 314001, P.R.China

Sterilization Method:
E.T.O. Sterilization

Qingdao, 03.03.2009



APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60024385 0001

Report No.: 15030316 001

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

Zhejiang 314001
China

Scope: Design and Development, Manufacture of Medical Devices

Products: see attachment
Sterilization Site and Method: see attachment

Replaces Approval, Registration No.: HD 60006996 0001

Date of Expiry: 02.03.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 03.03.2009



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with.

CE

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: **HD 60024385 0001**
Report No.: **15030316 001**

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

Scope:

Products:
- Spinal Needles
- Epidural Anaesthesia Kits
- Analgesia Infusion Pumps

Sterilization Site:
Zhejiang Sujia Medical Device Co., Ltd.
No.168, Zhenxing Rd., Jiaxing,
Zhejiang 314001, P.R.China

Sterilization Method:
E.T.O. Sterilization

Cologne, 03.03.2009



APPROVAL
EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60024386 0001

Report No.: 15030316 001

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

Zhejiang 314001
China

Scope: Manufacture of Medical Devices
Products: see attachment
Sterilization Site and Method: see attachment

Date of Expiry: 02.03.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 03.03.2009



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln

Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: DD 60024386 0001
Report No.: 15030316 001

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

Zhejiang 314001
China

Scope:

Products:

- Rigid Endoscopes
- Tracheal Tubes
- Laryngeal Mask Airway
- Steel-Reinforced Tracheal Tubes
- 3-Way Stopcocks
- Heparin Caps
- Tracheostomy Tubes
- Extension Tubes

Aspects of manufacture concerned with securing and maintaining sterile conditions:

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

Sterilization Site:

Zhejiang Sujia Medical Device Co., Ltd.
No.168, Zhenxing Rd., Jiaxing
Zhejiang 314001, P.R.China

Sterilization Method:

E.T.O.Sterilization



Cologne, 03.03.2009