



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 057924 0016 Rev. 00**

**Manufacturer:**

**Ningbo Advan Electrical Co., Ltd.**

Industrial Development Zone  
Fuhai Town  
315332 Cixi City, Ningbo, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**Product  
Category(ies):**

**Disposable Skin Stapler**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:**

SH19033EXT01

**Valid from:**

2019-10-16

**Valid until:**

2024-05-26

**Date,**

2019-10-16

Stefan Preiß  
Head of Certification/Notified Body





Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 057924 0016 Rev. 00**

**Facility(ies):**

**Ningbo Advan Electrical Co., Ltd.  
Industrial Development Zone, Fuhai Town, 315332  
Cixi City, Ningbo, Zhejiang Province, PEOPLE'S  
REPUBLIC OF CHINA**





**Ningbo Advan Electrical Co.,Ltd**

TEL: 86 574 58961012

FAX: 86 574 58961011

Website: www.advan-china.com

## **EC Declaration of Conformity**

**The below listed medical product(s) complies with the Medical Devices Directive No.93/42/EEC. The product(s) therefore fulfill all essential requirements for the application of the CE-conformity mark.**

**Revision number: DOC.REV.STAPLER.201901**

**Manufacturer** : Ningbo Advan Electrical Co., Ltd.  
Industrial Development Zone, Fuhai Town, 315332 Cixi City,  
Ningbo, Zhejiang Province, People's Republic of China

**Product type** : Disposable Skin Stapler

**Model No** : F-35W/F-35R

**Authorized EC Representative** : Shanghai International Holding  
Corp.GmbH (Europe)  
Eiffestrabe 80 20537 Hamburg GERMANY

**Notify Body &** : TÜV Product Service GmbH  
Rilerstrasse 65, 80339 München, Germany

**Certificate Details** : Identification No : 0123; Certificate No: G2 057924 0016 Rev. 00  
Date of Issue : 10.16.2019 Date of Expiry : 05.26.2024

**Class** : IIa (Rule VII)

**GMDN Codes** : 35884

**Conformity Assessment Route** : Annex V.3

**Directive & Standard Reference** : MDD 93/42/EEC AMENDED BY 2007/47/EC  
ISO 13485, ISO 14971, ISO 10993-7  
All applicable Harmonized EN Standards.

### **Australian Regulations:**

This is a declaration of conformity made under Clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Each kind of medical device to which the declaration of conformity procedures applies, the production quality assurance procedures have also been applied. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of essential principles, the classification rules, and these procedures.



-----  
**Vivian Liu ( Exporting Sale Director )     Date: April 17, 2020**  
**NINGBO ADVAN ELECTRICAL CO., LTD.**



# Certificate

No. Q6 057924 0014 Rev. 01

**Holder of Certificate:** **Ningbo Advan Electrical Co., Ltd.**

Industrial Development Zone  
Fuhai Town  
315332 Cixi City, Ningbo, Zhejiang Province  
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):**

Ningbo Advan Electrical Co., Ltd.  
Industrial Development Zone, Fuhai Town, 315332 Cixi City,  
Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

**Certification Mark:**



**Scope of Certificate:** **Production and Distribution of  
Disposable Skin Stapler,  
Remover for Skin Staples,  
Disposable Surgical Clipper Blade  
Assembly**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q6 057924 0014 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q6 057924 0014 Rev. 01)

**Report No.:** SH2003301

**Valid from:** 2021-06-11

**Valid until:** 2024-04-09

**Date,** 2021-06-11

Christoph Dicks  
Head of Certification/Notified Body



# GIMA

## DISPOSABLE STERILE SKIN STAPLER

**Code:** 25891  
**Category:** Sutures  
**Unit of sale:** box of 5 pcs.  
**Minimum order:** 1  
**Type:** Medical device  
**Class:** II A  
**NSIS:** 899174  
**CND:** H02010101  
**EAN13:** 8023279258912



**Description:** DISPOSABLE STERILE SKIN STAPLER - box of 5 pcs.

Simple and easy to operate. Staples are made of High Quality 317 L Stainless Steel for medical use, each device is provided of 35 staplers.

High sewing up and stapling speed help shorten the time of sewing and avoid cross infection of contagious diseases.

Reduced tissue reaction, thinner scar after operation and faster wound healing.

Painless and convenient staples removal after the incision has healed up.

To be used for skin closure in operating room, labour and delivery, emergency department, outpatient surgery, clinics and physician's office.

Multilanguage manual and box: GB, FR, IT, ES, PT, DE.