



**Ningbo Advan Electrical Co.,Ltd**

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## 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.



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