

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. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformation.

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-35R / F-35W

Authorized EC Representative : Shanghai International Holding
Corp.GmbH (Europe)
Eiffestrasse 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)

Conformity Assessment Route : Annex V.3

GMDN Codes : 35884

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



Vivian Liu (Exporting Sale Director)
NINGBO ADVAN ELECTRICAL CO., LTD.
Date: Feb 22th.2021