

CE Technical File

Declaration of Conformity

Manufacturer: Jiangsu Nanfang Medical Co. Ltd.

Address: No.1 Guoxiang Road, Wujin Economic Development Zone, Changzhou, Jiangsu, P,R,China

Authorized European representative: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestrasse 80, Hamburg, Germany

Product Name: Sterile Dressings Adhesive

Model Number: see List of CE-labeled Products

UMDNS Code: 10276

Classification (MDD, Annex IX): Class I Sterile, rule 4

Conformity Assessment Route: Annex V.3 +VII

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

We,as manufacturer, are exclusively responsible for this Doc.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 MÜNchen, Germany

NB Identification number: 0123

(EC) Certificate(s): G2S 063730 0012 Rev.01

Expire date of the Certificate: 2024-05-26

Signature:

Name : Ping Li

Position: General Manager

