

JIANGSU ZHENGKANG MEDICAL APPARATUS CO.,LTD



江苏正康医疗器械有限公司

Address: Sanhekou, Zhenglu town, Changzhou city, Jiangsu, china

TEL: +86-519-88672658 FAX: +86-519-88671088

EC Declaration of Conformity

Manufacturer: Jiangsu Zhengkang Medical Apparatus Co., Ltd
Sanhekou, Zhenglu town, Changzhou city, Jiangsu, china

Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Disposable Sterile Hypodermic Needles

Model Number: 0.4mm、0.45mm、0.5mm、0.55mm、0.6mm、0.7mm、0.8mm、0.9mm、1.0mm、
1.2mm
With the brand EuroMed

UMDNS code: 13929

Classification (MDD, Annex IX): IIa, rule 6

Conformity Assessment Route: Annex V.3

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.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Standard Applied: See attached list of (harmonised – EN) standards for which documented evidence of compliance can be provided.

Report No.: 713335548

Notified Body: TÜV SUD Product Service GmbH, Ridlerstrabe 65, 80339, München, Germany


Identification number: 0123

(EC) Certificate(s): CL 073425 0012 Rev 00

Expire date of the Certificate: 2028-12-31

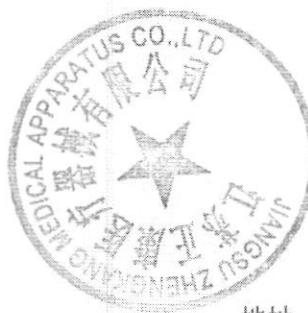
Start of CE Marking: 2024-05-21

Place, Date of Issue: Changzhou, 2024-05-21

Signature: 

Name: Songren. Xu

Position: General Manager



地址: 江苏省常州市郑陆三河口

Address: Sanhekou, Zhenglu town, Changzhou city, Jiangsu, china

电话 (TEL): +86-519-88672658 传真 (FAX): +86-519-88671088

E-mail: info@china-zhengkang.com 邮编 (Zip Code): 213115