

淮安市天达医疗器械有限公司

HuaiAn TianDa Medical Instruments Co.,Ltd.

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Declaration of Conformity

Manufacturer: HUAIAN TIANDA MEDICAL INSTRUMENTS CO.,LTD.

Add:No.106 East Songjiang Road,Huaiyin Economic&Technological Development Zone 223002 Huaian City,Jiangsu China

European Representative: Shanghai International Holding Corp. GmbH(Europe)

Add: Eiffestrasse 80, 20537 Hamburg, Germany

1)Product: Disposable Surgical blades(with and without handle)

Size: 10#,11#,,12#,12B#,13#,14#,15#,15C#,16#,18#,19#,20# , 21#, 22#, 23#, 24#, 25#,36#

UMDNS CODE:15558

Indication of use:

1) Disposable Surgical blades(with and without handle): Disposable surgical blades used chiefly to excise skin

Classification: Class IIb, rule 6

We herewith declare that the above mentioned products meet the provisions of Directive 93/42/EEC which apply to them, The Medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC,It bears the mark CE0197.

The product concerned has been manufactured under a quality management system according to Annex V& Annex VII of Directive 93/42/EEC.

DIRECTIVES

General Applicable Directive:

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

Notify Body: TUV Rheinland Product Safety GmbH, Am Grauen Stein,D-51105 Koln

Certificate: DD 60147743 0001

Date CE Certificate is Expired: 2024-05-26

Date CE mark was affixed: 2020-10-08

Place: HuaiAn JiangSu

Date: 2020-10-08

Signature:

Name: Chen Zhiyong

Position: General Manager

