

# 淮安市天达医疗器械有限公司

## HuaiAn TianDa Medical Instruments Co.,Ltd.

No.106 East Songjiang Road,Huaiyin Economic&Technological Development Zone 223002 Huaian City,Jiangsu China  
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### Declaration of Conformity

**Manufacturer:** HUIAN 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:** 2020-10-09

**Signature:**

**Name:** Chen Zhiyong

**Position:** General Manager

