

中国国际贸易促进委员会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书

CERTIFICATE



号码 No. 193100B0/007721

兹证明：在所附符合性声明上的淮安市海伦医疗器械有限公司的印章属实。

THIS IS TO CERTIFY THAT: the seal of Huaian Helen Medical Instrument Co., Ltd on the annexed DECLARATION OF CONFORMITY is genuine.

China Council for the Promotion
of International Trade

授权签字:

Authorized
Signature:

Zhou Pingfan

日期: 2019年05月06日

(Date: May. 06, 2019)

Declaration of Conformity

Manufacturer: Huaian Helen Medical Instruments Co., Ltd.

Group 3, Zhentai village Matou Town, Huaiyin district, Huaian City, Jiangsu, China

European Representative: Landlink GmbH
Dorfstrasse 2/4, 79312, Emmendingen, Germany

Tel: +0049-7641-9626855 Fax: +0049-7641-9626855

1) Product: Blood Lancets

Size: 21G, 23G, 26G, 28G, 30G

2) Product: Surgical blades

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

3) Product: Scalpels

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

Indication of use:

1) **Blood Lancets** Choose a meet size, according to the requirements of the sufferers. Dilacerate the packing and then use

2) **Surgical blades** Disposable surgical blades used chiefly to excise skin

3) **Scalpels** Dilacerate the packing and then use

Classification: Class IIa, rule 6

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directive and Standards. All supporting documentation are retained under the premise of manufacturer and the notify body.

DIRECTIVES

General Applicable Directive:

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

Standards:

All applicable harmonized standard (published in the Official Journal of the European Communities e.g. EN 552:1994+A1+A2, ISO 11137:1995+A1, EN 556-1:2001, EN ISO 14971:2000+A1:2003, EN 980:2003, EN 1041:1998, EN 868-1:1997, ISO 11607:2003, EN ISO 14644-1:1999, EN ISO 14644-2:2000, ISO 11737-1:1995, ISO 11737-2:1998, ISO 11737-3:2004, EN ISO 10993-1:2003, EN ISO 10993-5:1999, EN ISO 10993-10:2002, EN ISO 7153-1:2000.)

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

Certificate: DD 60134639 0001

Date CE Certificate is Expired: 2023-09-28

Date CE mark was affixed: 2018-12-21

Place: HUIAN JIANGSHU

Signature:

Name: Png jin wen

Position: General Manager



Yukarıdaki imza ve mühürün **Shanghai** Eyaleti Halk Hükümeti Dış İlişkiler Bürosu'na ait olduğu tasdik olunur.

Genel No : 25176600

Özel No : 2989

Tarih : 15.05.2019

T.C. ŞANHAY BAŞKONSOLOSLUĞU

S.Doğa ÖLMEZ
Vice Consul

