中国国际贸易促进委员会

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

> 证明书 CERTIFICATE



号码 No. 193100B0/007720

兹证明: 所附EC证书登记号DD 60134639 0001的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of EC CERTIFICATE Registration. No. DD 60134639 0001 is in conformity with the original.

China Council for the Promotion of International Trade

授权签字:

Authorized

Zhou Pingfan

Signature:

日期: 2019年05月06日 (Date: May. 06, 2019)

证明书查询网址 Website for verifying the certificate: http://www.rzccpit.com/validate.html

TÜVRheinland

EC Certificate Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices

Registration No.:

DD 60134639 0001

Report No.:

15096311 002

Manufacturer:

Huaian Helen Medical Instrument

Co., Ltd.

Group 3, Zhengtai Village Matou Town, Huaiyin District

Huaian

223345 Jiangsu

China

Products:

- Sterile Blood Lancets

- Disposable Surgical Blades & Scalpels with Plastic Handle

Expiry Date:

2023-09-28

The Notified Body, hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date:

2018-12-21

Date:

2018-12-21

Notified Body

TÜVRheinland

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.



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

Genel No: 25176604 Özel No: 2990

Özel No: 2990 Tarih : 15.05.2019

T.C. ŞANHAY BAŞKONSOLOSLU

Vice Consult