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
TÜV Rheinland LGA Products GmbH
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.