EC Certificate

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

Registration No.: DD 60127363 0001

Report No.: 15056609 007

Manufacturer:
Huaian Hening Medical Instruments Co., Ltd.
No.6 West Hongdou Road, Economic & Technological Development Zone
223005 Huaian, Jiangsu
China

Digitally signed by Rotari Vladimir
Date: 2022.09.13 22:02:00 EEST
Reason: MoldSign Signature
Location: Moldova

Products:
- Sterile Blood Lancets

Aspects of manufacture concerned with securing and maintaining sterile conditions:
- Sterile Umbilical Cord Clamps
- Alcohol Pads

Replaces Approval, Registration No.: DD 60082383 0001

Expiry Date: 2023-02-19

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: 2018-03-19

Date: 2018-03-19

Notified Body
TÜV Rheinland LGA Products GmbH Zertifizierungsstelle
X. Ren

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.