EC Certificate

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

Registration No.: DD 60128928 0001

Report No.: 50118657 002

Manufacturer:
Zhejiang HaiChuang Medical
Device Co., Ltd.
1st Floor, 146 East ChaoFeng Rd.
Yuhang Economic and Technological
Development Area, Yuhang District
Hangzhou
311100 Zhejiang
China

Products:
Aspects of manufacture concerned with securing and maintaining sterile conditions:
- Wound Drainage Tube Fixing Devices

Expiry Date: 2023-06-20

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: 2018-07-27

Date: 2018-07-27

Notified Body

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.