

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4 Full Quality Assurance System Medical Devices

Registration No.: HD 60131017 0001

Report No.: 15062970 008

Manufacturer: Jinhua Huacheng Medical

Appliance Co., Ltd.
No. 186 Qingyu Road
Jindong Industrial Park

Jinhua City 321000 Zhejiang

China

Products: - Disposable Surgical Active Electrodes (Electrosurgical

Pencils)

- Disposable Neutral Electrodes

- Disposable Skin Staplers

Replaces Approval, Registration No.: HD 60088776 0001

Expiry Date: 2023-09-17

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-09-18

Date: 2018-09-05

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.