

EC Certificate

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

Registration No.: HD 60114587 0001

Report No.: 15095997 002

Manufacturer: CATHAY Manufacturing Corp.

No.328 Xishe Road

Maogang Town, Songjiang Area

201607 Shanghai

China

Products:

- Sterile Electrosurgical Pencils

- Disposable Neutral Electrodes

- TENs Electrodes

Replaces Approval, Registration No.: HD 60101752 0001

Expiry Date:

2021-11-02

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:

2016-11-03

Date:

2016-10-21

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Notified Book

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