EC Certificate

TÜVRheinland

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

Registration No.: HD 60110014 0001

Report No.: 15085675 001

Manufacturer:
Changzhou Medical Appliances
General Factory Co., Ltd.
Hengshanqiao Town, Wujin District
Changzhou
213119 Jiangsu
China

Products:
Disposable Circular Staplers, Disposable Linear Staplers, Disposable Linear Cutter Staplers, Disposable PPH Staplers, Hernia Surgical Mesh

Expiry Date: 2020-10-30

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: 2015-05-30

Date: 2015-05-30

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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