

EC Certificate

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

Registration No.: HD 60128425 0001

Report No.:

15096250 002

Manufacturer:

Yancheng Huida Medical Instruments

Co., Ltd.

No. 2, Kuiyuan Road

Xuefu Town, Yandu District

Yancheng City 224035 Jiangsu

China

Products:

Surgical Needles with Nonabsorbable Sutures

TUVRheinland

Expiry Date:

2023-05-09

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:

2018-05-10

Date:

2018-05-10

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.

Notified BodyGA P