

TÜVRheinland

X. Ren

EC Certificate

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

Registration No.: DD 60104764 0001

Report No.:

17047222 001

Manufacturer:

Yafho Bio-Technology Co., Ltd. Second Floor Room 202 and

Third Floor

No. 81, Junfeng Road, Huangpu District

Guangzhou

510760 Guangdong

China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions of Wound Dressings,

Surgical Drapes

Replaces Approval, Registration No.: DD 60074974 0001

Expiry Date:

2020-09-18

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:

2015-12-15

Date:

2015-12-15

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.