

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

Registration No.: HD 60142092 0001

Report No.: 15095988 008

Manufacturer: Jiangsu BANA Medical Technology
Co., Ltd.
No. 28-3 Guihua Road
Zhonglou Economic Development Zone
Changzhou
213013 Jiangsu
P.R. China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: HD 60138384 0001

Expiry Date: 2024-05-26

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: 2020-11-21

Date: 2020-11-21

Notified Body

Fuxiu Sheng



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.