

EC Certificate

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

Registration No.: HD 60127425 0001

Report No.: 15096255 002

Manufacturer: Zhejiang Baitai Medical Technology

Co., Ltd.

No. 1, Longjing Road, Jinchuan Street

Changshan County

Quzhou

324200 Zhejiang

China

Products: - Steam Sterilizers

Expiry Date: 2023-04-11

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: 2018-04-16

Date: 2018-04-16

TOV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜVRheinlan

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