

EC Certificate

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

Registration No.: HD 60112318 0001

Report No.: 15053953 004

Manufacturer: Ningbo Ican Machines Co., Ltd.

No.77, Yunlin East Road Gulin Town, Yinzhou District

315176 Ningbo

China

Products: Steam Sterilizers

Replaces Approval, Registration No.: HD 60079399 0001

Expiry Date: 2017-11-22

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: 2016-07-20

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TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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