

EC Certificate

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

Registration No.: HD 60123652 0001

Report No.: 15054160 016

Manufacturer: CHISON Medical Technologies

Co., Ltd.

No.228, Changjiang East Road

Block 51 and 53

Phase 5, Shuofang Industrial Park

Xinwu District

Wuxi

214142 Jiangsu

Products: China

Ultrasound Diagnostic Systems

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60123468 0001

Expiry Date: 2022-11-14

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:

2017-11-15

Date:

2017-11-06

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Notified Body

TÜVRhainlan

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



Doc. 1/1, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

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CHISON Medical Technologies

Co., Ltd.

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Xinwu District

Wuxi

214142 Jiangsu

China

Site included:

No.9, Xinhuihuan Road, Xinwu District, Wuxi, 214028 Jiangsu, China

Date: 2017-11-06

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