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
China

Products:
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 Notified Body TÜVRheinland S. Liu Zertifizierungsstelle

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.

Digitally signed by Ermicev Alexandr
Date: 2019.04.05 14:07:12 EEST
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to
Certificate
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
China

Site included:

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

Date: 2017-11-06

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Notified Body
Zertifizierungsstelle
S. Liu