

**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)

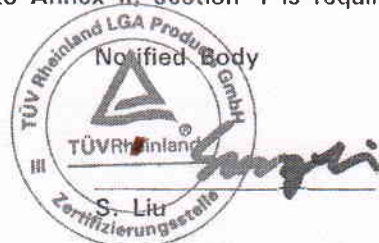
Replaces Approval, Registration No.: HD 60123468 0001

**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**

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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**Report No.:** 15054160 016

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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**

