

**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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**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



Shanghai, 2017-11-14

**To Whom It May Concern:**

This is to confirm that the Full Quality Assurance System--- MDD 93/42/EEC Annex II certificate

*Manufacturer:* CHISON Medical Technologies Co., Ltd.  
*Add.:* No.228, Changjiang East Road, Block 51 and 53, Phase 5,  
Shuofang Industrial Park, Xinwu District, Wuxi, 214142 Jiangsu,  
China  
*Products:* Ultrasound Diagnostic Systems  
*Registraton No:* HD 60123652 0001

for the following information concerning the products listed as follows:

**Name of the product**

*Ultrasound Diagnostic Systems*

**Models:**

CHISON600M, CHISON8300, CHISON8500,  
CHISON8800, CHISON9500, CHISON9300,  
CHISON9100, SONOTOUCH10, SONOTOUCH20,  
SONOTOUCH30, SONOTOUCH50, SONOTOUCH60,  
SONOTOUCH80, CHISON iVis60, CHISON  
iVis60EXPERT, CHISON iVis20, CHISON iVis30, CHISON  
iVis50, i3, i6, i7, i8, i9, ECO 1, ECO 2, ECO 3, ECO 4,  
ECO 5, ECO 6, Q1, Q2, Q3, Q4, Q5, Q6, Q8, Q9, Q10,  
ECO 1 EXPERT, ECO 2 EXPERT, ECO 3 EXPERT, ECO 4  
EXPERT, ECO 5 EXPERT, ECO 6 EXPERT, QBit 1, QBit 2,  
QBit 3, QBit 4, QBit 5, QBit 6, QBit 7, QBit 8, QBit 9,  
QBit 10, QBit 11, QBit 12, EBit 10, EBit 20, EBit30, EBit  
40, EBit 50, EBit 60, EBit 70, EBit 80, EBit 90,  
SonoBook 1, SonoBook 2, SonoBook 3, SonoBook 4,  
SonoBook 5, SonoBook 6, SonoBook 7, SonoBook 8,  
SonoBook 9, Site~Rite Halcyon

Yours sincerely,

TÜV Rheinland (Shanghai) Co., Ltd.



Mr. Allen CHEN  
Lead Auditor  
Medical Services



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(Shanghai) Co., Ltd.

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