

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



TÜV Rheinland
(Shanghai) Co., Ltd.

TUV Building,
No.177, Lane 777,
West Guangzhong Road,
Shanghai 200072,
P.R.China

Tel. +86 - 21 - 6108 1188
Fax +86 - 21 - 6108 1099
+86 - 21 - 6108 1199

Hotline
800 999 3668/400 883 1300
service-gc@tuv.com

www.tuv.com