

Shanghai, 2022-03-29

To Whom It May Concern:

This is to confirm that the Full Quality Assurance System -- MDD 93/42/EEC Annex II
excluding (4) certificate

Manufacturer: CHISON Medical Technologies Co., Ltd.
Add.: No. 3, Changjiang South Road, Xinwu District, Wuxi, 214028
Jiangsu, P.R. China
Products: Ultrasound Diagnostic Systems
Registraton No: HD 60147775 0001

for the following information concerning the products listed as follows:

<u>Name of the product</u>	<u>Models:</u>
<i>Ultrasound Diagnostic Systems</i>	XBit 20, XBit 30, XBit 40, XBit 50, XBit 60, XBit 70, XBit 80, XBit 90

Yours sincerely,

TÜV Rheinland (Shanghai) Co., Ltd.



Mr. Tony CHEN
Location Field Manager
Medical Services

TÜV Rheinland
(Shanghai) Co., Ltd.

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

Registration No.: HD 60147775 0001

Report No.: 15054160 024

Manufacturer: CHISON Medical Technologies
Co., Ltd.
No.228, Changjiang East Road
Block 51 and 53
Phase 5, Shuofang Industrial Park
Xinwu District
Wuxi

Products: 214142 Jiangsu
P.R. China
Ultrasound Diagnostic Systems

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60123652 0001

Expiry Date: 2024-05-26

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: 2020-04-03

Date: 2020-04-03

Notified Body

Jason Pan



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 60147775 0001
Report No.: 15054160 024

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
P.R. China

Site included:

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

Date: 2020-04-03

Notified Body

Jason Pan



Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2102189-1

Organization: CHISON Medical Technologies Co., Ltd.
No.3 Changjiang South Road,
Xinwu District, Wuxi,
214028 Jiangsu
P.R. China

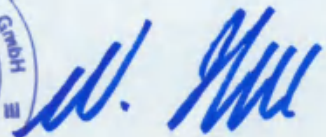
Scope: Design and Development, Manufacture and Distribution of Ultrasound Diagnostic Systems;
And the capability of Design and Development, Manufacture and Distribution of Veterinary Ultrasound Diagnostic Systems



TÜVRheinland®

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244379887-200
Effective date: 2022-02-14
Expiry date: 2023-11-14
Issue date: 2022-02-14



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

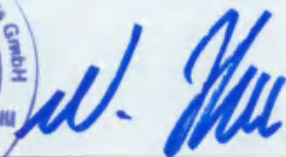
Registration No.: SX 2102189-1

Organization: CHISON Medical Technologies Co., Ltd.
No.3 Changjiang South Road,
Xinwu District, Wuxi,
214028 Jiangsu
P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o CHISON Medical Technologies Co., Ltd. No.3 Changjiang South Road, Xinwu District, Wuxi, 214028 Jiangsu P.R. China	Manufacture of Ultrasound Diagnostic Systems; And the capability of Design and Development, Manufacture and Distribution of Veterinary Ultrasound Diagnostic Systems
/02	c/o CHISON Medical Technologies Co., Ltd. No.9, Xinhuihuan Road, Xinwu District, Wuxi, 214028 Jiangsu P.R. China	Design and Development, Distribution of Ultrasound Diagnostic Systems; And the capability of Design and Development, Manufacture and Distribution of Veterinary Ultrasound Diagnostic Systems

Report No.: 244379887-200
Effective date: 2022-02-14
Expiry date: 2023-11-14
Issue date: 2022-02-14

Dipl.-Ing. W. Hsu
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CHISON Medical Technologies Co., Ltd.
No.3 Changjiang South Road,
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214028 Jiangsu
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com
Date February 22, 2022

Application for : QMS
Certificate No. : HD 60147775 0001
Requirement : Richtlinie 93/42/EWG
Confirmation letter ID : 2020-04-03_ HD 60147775 0001
Report no. : 244379887-200

Dear Madame or Sir,

Update of information to Certificate no. HD 60147775 0001, issued on 14.02.2022

The change notification received on 25.08.2021 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.

We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer address

Old Manufacturer address: No.228, Changjiang East Road, Block 51 and 53, Phase 5, Shuofang Industrial Park, Xinwu District, Wuxi, 214142 Jiangsu, P.R. China

New Manufacturer address: No.3 Changjiang South Road, Xinwu District, Wuxi, 214028 Jiangsu, P.R. China

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VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

Best regards,


Dipl.-Ing. W. Hsu
Certification body

MS-0045448 rev.0