

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

Doc. 1/1, Rev. 0

**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



TÜV Rheinland LGA Products GmbH • 51105 Köln

CHISON Medical Technologies Co., Ltd.
No.3 Changjiang South Road,
Xinwu District, Wuxi,
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

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

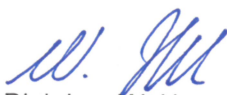
Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

Best regards,



Dipl.-Ing. W. Hsu
Certification body

MS-0045446 rev.0

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Chison Medical Technologies Co.,Ltd.

Shanghai International Holding
Corp.GmbH(Europe)

No.3 Changjiang South Road,
Xinwu District, Wuxi, 214028

Eiffestrasse 80,20537Hamburg,Germany
DIMDI NO.:DE/0000040627

Jiangsu, P.R. China

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

We, the manufacturer, herewith declare that the products
Ultrasound Diagnostic Systems

Model: ECO2, ECO6, QBit 5, QBit 7

UMDNS-Code: **15976**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex II of the
Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according
to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and
certified by the Notified Body

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

Certificate No.: HD 60147775 0001

Issue date: 03.04.2020

Expiry date: 26.05.2024

following the procedure relating to the EC Declaration of Conformity set out in Annex II of
Directive 93/42/EEC.

06.12.2022

Liu Qifei



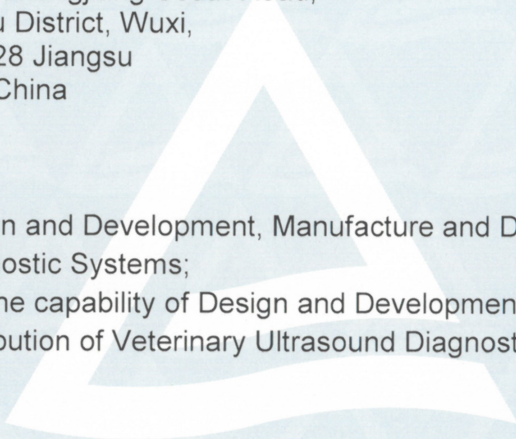
Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2102189-1

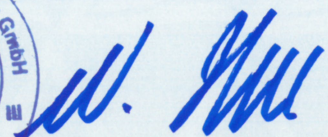
Organization: CHISON Medical Technologies Co., Ltd.
No.3 Changjiang South Road,
Xinwu District, Wuxi,
214028 Jiangsu
P.R. China

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

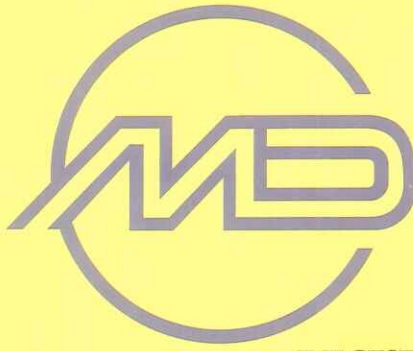
Registration No.: SX 2102189-1

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



REGISTRATION NO. 04720Q10570R5M

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

This is to certify that the quality management system of

CHISON Medical Technologies Co., Ltd.

Registered Address: No.3, Changjiang South Road, Xinwu District, Wuxi

Manufacturing Address: No.3, Changjiang South Road, Xinwu District, Wuxi, Jiangsu

Has been assessed and conformed to the following standard(s)

GB/T 19001-2016 idt ISO 9001:2015

The certificate is valid for the following scope:

The certificate covers the design, development, manufacture and service of Digital Color Doppler Ultrasound System, Digital Color Doppler Palm Ultrasound System.

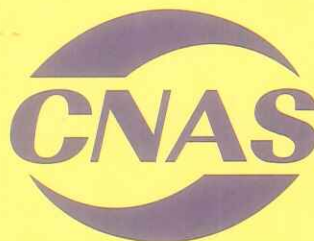
Date of issue: January 05, 2021

Date of expiry: January 04, 2024

Date of change: January 14, 2022

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**



中国认可
国际互认
管理体系

MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (<http://www.cnca.gov.cn>) or the website of CMD (<http://www.cmdc.com.cn>). Address: 5th floor of Zhong Lian building, No. jia88, An Ding Men Wai street, Dongcheng district, Beijing, 100011, P.R. China Telephone: 010-62351993