

Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

CHISON Medical Technologies Co., Ltd. No.228, Changjiang East Road Block 51 and 53 Phase 5, Shuofang Industrial Park Xinwu District 214142 Wuxi Jiangsu

has established and applies a quality management system for medical devices for the following scope:

(see attachment for scope and additional site included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:

2017-11-15

Certificate Registration No.:

SX 60123653 0001

An audit was performed. Report No. 15054160 016

This Certificate is valid until:

2020-11-14



Date 2017-11-06



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.:

SX 60123653 0001

Report No.:

15054160 016

Organization:

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

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

Site included:

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

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

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2017-11-06

Certification Body

