Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2102189-1

Certificate Holder: 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

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.: 244519700-200

Effective date: 2023-11-15
Expiry date: 2026-11-14
Issue date: 2023-10-26

Replaces certificate SX 2102189-1 issued 2022-02-14

Jason Pan

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

This certificate can be validated on https://www.certipedia.com





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Quality Management System EN ISO 13485:2016

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No.3 Changjiang South Road,

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The scope of certification also covers the following sites:

No. **Facility** Scope

c/o CHISON Medical Technologies Co., Ltd. No.3 Changjiang South Road,

Xinwu District, Wuxi, 214028 Jiangsu P.R. China

/02 c/o CHISON Medical Technologies Co., Ltd.

No.9, Xinhuihuan Road, Xinwu District,

214028 Jiangsu P.R. China

Aspects related to Manufacturing

Aspects related to Design and Development

and Distribution

Report No .: 244519700-200 Effective date: 2023-11-15 Expiry date: 2026-11-14

2023-10-26

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Issue date: