Business Stream Products
Certification Department

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Precisely Right.

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

Best regards,

Dipl.-Ing. W. Hsu
Certification body
MS-0045446 rev.0

TÜV Rheinland
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51105 Köln
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90431 Nuremberg

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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
214142 Jiangsu
P.R. China

Products:
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 Zertifizierungsstelle

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.

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Doc. 1/1, Rev. 0

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

Notified Body

Jason Pan

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-04-03