Business Stream Products
Certification Department

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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
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

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Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

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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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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

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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 July 10, 2024

Notified Body Confirmation Letter
Reference. : PLA dated 2024-02-29; order # 326036762

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

CHISON Medical Technologies Co., Ltd.
No.3 Changjiang South Road, Xinwu District,
Wuxi,214028 Jiangsu,
P.R.China
SRN Number (if available): CN-MF-000021605

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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Dr.-Ing. Michael Fübi

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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Jason Pan
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Ultrasound Diagnostic System Basic UDI-DI: 69451214XBitYH	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214CBitTW	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214SonoBookRK	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214EBitUC	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System	Class IIa	N/A	Certificate #: HD 60147775 0001

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 69451214QBitWY			NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214SonoAirZL	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214P1CG	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214P2CJ	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214P3CL	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214P5CQ	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214P6CS	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214SonoMax37	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197
Ultrasound Diagnostic System Basic UDI-DI: 69451214ECOYA	Class IIa	N/A	Certificate #: HD 60147775 0001 NB# 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
None			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-07-10	PLA dated 2024-02-29; order # 326036762	Initial issue