Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Changzhou Jiuhong Medical Instrument Co., Ltd.
No.256, Mingxin Middle Road, Wujin District,
Changzhou,
213164 Jiangsu,
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 10, 2024

Notified Body Confirmation Letter
Reference. : 326015608

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:

Changzhou Jiuhong Medical Instrument Co., Ltd.
No.256, Mingxin Middle Road, Wujin District,
Changzhou, 213164 Jiangsu,
P.R. China
SRN Number: CN-MF-000016791

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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.

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

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

Fuxiu Sheng
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**
Injection Needle Basic UDI-DI: 69420002044NB	Class IIa	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002002MT	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002003MV	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002004MX	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002005MZ	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002006N3	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197

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
Biopsy Valve Basic UDI-DI: 69420002007N5	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002008N7	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002009N9	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002010MS	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002011MU	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002012MW	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002013MY	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002014N2	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Biopsy Valve Basic UDI-DI: 69420002015N4	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Dilation Balloon Basic UDI-DI: 69420002016N6	Class IIa	Gastrointestinal and Biliary Balloon Catheters	Certificate #HD 2029448-1; NB# 0197
Dilation Balloon Basic UDI-DI: 69420002069NT	Class IIa	Gastrointestinal and Biliary Balloon Catheters	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002017N8	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002018NA	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197

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
Disposable Biopsy Forceps Basic UDI-DI: 69420002019NC	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002020MV	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002021MX	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002022MZ	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002023N3	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002024N5	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002025N7	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002026N9	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002027NB	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002028ND	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Biopsy Forceps Basic UDI-DI: 69420002029NF	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197

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
Disposable Biopsy Forceps Basic UDI-DI: 69420002030MY	Class IIa	Disposable Non-electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002031N2	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002032N4	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002033N6	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002034N8	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002035NA	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002036NC	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002037NE	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002038NG	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002067NP	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002039NJ	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197

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
Disposable Grasping Forceps Basic UDI-DI: 69420002040N3	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002041N5	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002042N7	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Grasping Forceps Basic UDI-DI: 69420002043N9	Class IIa	Grasping Forceps	Certificate #HD 2029448-1; NB# 0197
Non-vascular Guidewire Basic UDI-DI: 69420002047NH	Class IIa	N/A	Certificate #HD 2029448-1; NB# 0197
Non-vascular Guidewire Basic UDI-DI: 69420002048NK	Class IIa	N/A	Certificate #HD 2029448-1; NB# 0197
Non-vascular Guidewire Basic UDI-DI: 69420002049NM	Class IIa	N/A	Certificate #HD 2029448-1; NB# 0197
Bougie Dilator Basic UDI-DI: 69420002050N6	Class IIa	Bougie Dilator Sets	Certificate #HD 2029448-1; NB# 0197
Balloon Inflator Basic UDI-DI: 69420002051N8	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Disposable Cytology Brush Basic UDI-DI: 69420002053NC	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Disposable Cytology Brush Basic UDI-DI: 69420002054NE	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Disposable Cytology Brush	Class I devices placed on the	N/A	Certificate #HD 2029448-1;

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: 69420002055NG	market in sterile condition		NB# 0197
Disposable Cytology Brush Basic UDI-DI: 69420002065NK	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Disposable Cytology Brush Basic UDI-DI: 69420002066NM	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Disposable Endoscopic Hemoclip Basic UDI-DI: 69420002056NJ	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate #HD 2029448-1; NB# 0197
Disposable Stone Extraction Basket Basic UDI-DI: 69420002057NL	Class IIa	Stone Extraction Baskets	Certificate #HD 2029448-1; NB# 0197
Disposable Stone Extraction Basket Basic UDI-DI: 69420002058NN	Class IIa	Stone Extraction Baskets	Certificate #HD 2029448-1; NB# 0197
Disposable Stone Extraction Balloon Basic UDI-DI: 69420002059NQ	Class IIa	Stone Extraction Balloons	Certificate #HD 2029448-1; NB# 0197
Disposable Polypectomy Snare Basic UDI-DI: 69420002060N9	Class IIb excluding Class IIb implantable non-WET	Disposable Polyp Snares	Certificate #HD 2029448-1; NB# 0197
Disposable Polypectomy Snare Basic UDI-DI: 69420002061NB	Class IIb excluding Class IIb implantable non-WET	Disposable Polyp Snares	Certificate #HD 2029448-1; NB# 0197
Disposable Polypectomy Snare Basic UDI-DI: 69420002062ND	Class IIb excluding Class IIb implantable non-WET	Disposable Polyp Snares	Certificate #HD 2029448-1; NB# 0197
Disposable Polypectomy Snare Basic UDI-DI: 69420002063NF	Class IIb excluding Class IIb implantable non-WET	Disposable Polyp Snares	Certificate #HD 2029448-1; NB# 0197
Disposable Polypectomy Snare	Class IIb excluding Class IIb	Disposable Polyp Snares	Certificate #HD 2029448-1;

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: 69420002064NH	implantable non-WET		NB# 0197
Kyphoplasty Balloon Catheter Basic UDI-DI: 69420002053NC	Class IIa	N/A	Certificate #HD 2029448-1; NB# 0197
Multiple Band Ligator Basic UDI-DI: 69420002077NS	Class IIa	N/A	Certificate #HD 2029448-1; NB# 0197
Disposable Hot Biopsy Forceps Basic UDI-DI: 69420002078NU	Class IIb excluding Class IIb implantable non-WET	Disposable Electric Biopsy Forceps	Certificate #HD 2029448-1; NB# 0197
Disposable Bite Block Basic UDI-DI: 69420002079NW	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Cleaning Brush Basic UDI-DI: 69420002070NC	Class I devices placed on the market in sterile condition	Cleaning Brushes for Endoscope	Certificate #HD 2029448-1; NB# 0197
Polyp Trap Basic UDI-DI: 69420002071NE	Class I devices placed on the market in sterile condition	N/A	Certificate #HD 2029448-1; NB# 0197
Percutaneous needle Basic UDI-DI: 69420002072NG	Class IIa	Balloon Kyphoplasty Kits	Certificate #HD 2029448-1; NB# 0197
Expansion cannula Basic UDI-DI: 69420002073NJ	Class IIa	Balloon Kyphoplasty Kits	Certificate #HD 2029448-1; NB# 0197
Guide wire Basic UDI-DI: 69420002074NL	Class IIa	Balloon Kyphoplasty Kits	Certificate #HD 2029448-1; NB# 0197
Expansion bone drill Basic UDI-DI: 69420002075NN	Class IIa	Balloon Kyphoplasty Kits	Certificate #HD 2029448-1; NB# 0197
Bone cement filler Basic UDI-DI: 69420002076NQ	Class IIa	Balloon Kyphoplasty Kits	Certificate #HD 2029448-1; 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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-05-10	326015608	Initial issue