# Certificate

## Quality Management System
## EN ISO 13485:2016

| | |
|---|---|
| Registration No.: | SX 2041633-1 |
| Certificate Holder: | Jiangsu Rongye Technology Co., Ltd.<br>Touqiao Town, Yangzhou City<br>225109 Jiangsu<br>P.R. China |
| Scope: | Design and Development, Manufacture and Distribution of Otolaryngological Sets for Single use, Liquid Drainage Devices, Amniotic Membrane Perforators for single use, Gynecologic Samplers for single use, Blood Collection Needles for single use, Infusion Sets for single use, Syringes for single use, Stomach Tubes for single use, Nelaton Catheters for single use, Nasal Oxygen Tubes, Three-way Stopcocks (with Extension tubes), Needle Free Connectors, Umbilical Cord Clamps for Single Use, Gynecological Sets for Single Use, Vaginal Speculums for Single Use, Tongue Depressors for Single Use, Ear Checkers for Single Use, Medical Suction-connecting Tubes for single use, Plastic Forceps, Medical Cups for single use, Urinary Drainage Bags for single use, Nasal Speculums, I.D. Bracelets for single use, Suction Catheters for single use, Medical Tapes, Wound Plasters, Skin Knives, Medical brushes, Tourniquets, Disposable Surgical Blades (with and without handle), Sterile Surgical Packs, Disposable Dressing Kits, Face Masks, Oxygen Masks for single use, Venturi Masks for single use, Nebulizer Masks for single use, Oxygen Masks with Reservoir Bags for single use, Nebulizers with Mouth-pieces, Anesthesia Masks, Blood Collection Tubes, Viral Transport Kits, Viral |

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.: | 326020254-200 |
| Effective date: | 2024-07-14 |
| Expiry date: | 2027-07-13 |
| Issue date: | 2024-06-20 |

Replaces certificate SX 2041633-1 issued 2021-07-22

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

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







DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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# Certificate

## Quality Management System
## EN ISO 13485:2016

| | |
|---|---|
| Registration No.: | SX 2041633-1 |
| Certificate Holder: | Jiangsu Rongye Technology Co., Ltd.<br>Touqiao Town,<br>Yangzhou City<br>225109 Jiangsu<br>P.R. China |
| | Transport Tubes, Specimen Collection Swabs, Disposable Enteral Feeding Sets, Disposable Surgical Gowns, Medical Bandages, Medical Gauzes |

| | |
|---|---|
| Report No.: | 326020254-200 |
| Effective date: | 2024-07-14 |
| Expiry date: | 2027-07-13 |
| Issue date: | 2024-06-20 |

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# EC Certificate

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**Production Quality Assurance**
**MDD Annex V**

Registration No.: DD 2041633-1

Manufacturer: Jiangsu Rongye Technology Co., Ltd.
Touqiao Town,
Yangzhou City
225109 Jiangsu
P.R. China

Products: Amniotic Membrane Perforators for single use, Gynecologic Samplers for single use, Blood Collection Needles for single use, Infusion Sets for single use, Syringes for single use, Nelaton Catheters for single use, Nasal Oxygen Tubes, Three-way Stopcocks (with Extension tubes), Needle Free Connectors, Disposable Surgical Blades (with and without handle);

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

Otolaryngological Sets for single use, Liquid Drainage Devices, Stomach Tubes for single use, Umbilical Cord Clamps for Single Use, Gynecological Sets for Single Use, Vaginal Speculums for Single Use, Tongue Depressors for Single Use, Ear Checkers for Single Use, Plastic Forceps, Medical Cups for single use, Urinary Drainage Bags for single use, Nasal Speculums, I.D. Bracelets for single use, Suction Catheters for single use, Medical Tapes, Wound Plasters, Medical brushes, Medical Suction connecting Tubes for single use, Sterile Surgical Packs, Disposable Dressing Kits, Specimen Collection Swabs

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15082365 012

Effective date: 2020-12-02

Expiry date: 2024-05-26

Issue date: 2020-12-02

TÜV Rheinland LGA Products GmbH

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**Business Stream Products**
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

Jiangsu Rongye Technology Co., Ltd.
Touqiao Town, Yangzhou City,
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P.R. China

Contact

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

Date April 28, 2024

**Notified Body Confirmation Letter**
Reference. : 326013431

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:

Jiangsu Rongye Technology Co., Ltd.
Touqiao Town, Yangzhou City,
225109 Jiangsu,
P.R. China
SRN Number: CN-MF-000019627

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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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** |
|---|---|---|---|
| Otolaryngological set for single use<br><br>Basic UDI-DI code: 697065458MD3101CX | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Liquid drainage device<br><br>Basic UDI-DI code: 697065458MD3102CZ | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Amniotic Membrane Perforators for single use<br><br>Basic UDI-DI code: 697065458MD3103D3 | Class IIa | N/A | DD 2041633-1 #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** |
|---|---|---|---|
| Gynecologic samplers for single use<br><br>Basic UDI-DI code: 697065458MD3104D5 | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Blood collection needles for single use<br><br>Basic UDI-DI code: 697065458MD3105AF4 | Class IIa | N/A | DD 2041633-1 #0197 |
| Blood collection needles for single use<br><br>Basic UDI-DI code: 697065458MD3105BF6 | Class IIa | N/A | DD 2041633-1 #0197 |
| Blood collection needles for single use<br><br>Basic UDI-DI code: 697065458MD3105CF8 | Class IIa | N/A | DD 2041633-1 #0197 |
| Blood collection needles for single use<br><br>Basic UDI-DI code: 697065458MD3105DFA | Class IIa | N/A | DD 2041633-1 #0197 |
| Infusion Sets for single use<br><br>Basic UDI-DI code: 697065458MD3106D9 | Class IIa | N/A | DD 2041633-1 #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 |
|---|---|---|---|
| Syringes for single use<br><br>Basic UDI-DI code: 697065458MD3107DB | Class IIa | N/A | DD 2041633-1 #0197 |
| Stomach Tubes for single use<br><br>Basic UDI-DI code: 697065458MD3108DD | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Nelaton Catheters for single use<br><br>Basic UDI-DI code: 697065458MD3109DF | Class IIa | N/A | DD 2041633-1 #0197 |
| Nasal oxygen tubes<br><br>Basic UDI-DI code: 697065458MD3110CY | Class IIa | N/A | DD 2041633-1 #0197 |
| Three-way stopcocks(with extension tube)<br><br>Basic UDI-DI code: 697065458MD3111D2 | Class IIa | N/A | DD 2041633-1 #0197 |
| Needle Free connectors<br><br>Basic UDI-DI code: 697065458MD3112D4 | Class IIa | N/A | DD 2041633-1 #0197 |
| Umbilical cord clamps for single use<br><br>Basic UDI-DI code: 697065458MD3113D6 | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #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 |
|---|---|---|---|
| Gynecological sets for single use<br><br>Basic UDI-DI code: 697065458MD3114D8 | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Vaginal speculums for single use<br><br>Basic UDI-DI code: 697065458MD3115DA | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Tongue depressors for single use<br><br>Basic UDI-DI code: 697065458MD3116DC | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Ear checkers for single use<br><br>Basic UDI-DI code: 697065458MD3117DE | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Medical suction-connecting tubes for single use<br><br>Basic UDI-DI code: 697065458MD3118DG | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Plastic forceps<br><br>Basic UDI-DI code: 697065458MD3119DJ | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Medical Cups for single use<br><br>Basic UDI-DI code: 697065458MD3120D3 | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #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 |
|---|---|---|---|
| Urinary drainage bags for single use<br><br>Basic UDI-DI code: 697065458MD3121D5 | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Nasal speculums<br><br>Basic UDI-DI code: 697065458MD3122D7 | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| I.D.Bracelets for single use<br><br>Basic UDI-DI code: 697065458MD3123D9 | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Suction Catheters for single use<br><br>Basic UDI-DI code: 697065458MD3124DB | Class IIa | N/A | DD 2041633-1 #0197 |
| Medical Tapes<br><br>Basic UDI-DI code: 697065458MD3125DD | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Wound Plasters<br><br>Basic UDI-DI code: 697065458MD3126DF | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Medical Brushes<br><br>Basic UDI-DI code: 697065458MD3128DK | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #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 |
|---|---|---|---|
| Sterile Surgical Packs<br><br>Basic UDI-DI code: 697065458MD3131D8 | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Disposable Dressing kits<br><br>Basic UDI-DI code: 697065458MD3132DA | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Disposable surgical blades(with or without handle)<br><br>Basic UDI-DI code: 697065458MD3130D6 | Class IIa | N/A | DD 2041633-1 #0197 |
| Specimen collection swabs<br><br>Basic UDI-DI code: 697065458MD3143AFJ | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Specimen collection swabs<br><br>Basic UDI-DI code: 697065458MD3143BFL | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Specimen collection swabs<br><br>Basic UDI-DI code: 697065458MD3143CFN | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #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 |
|---|---|---|---|
| Specimen collection swabs<br><br>Basic UDI-DI code: 697065458MD3143DFQ | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Specimen collection swabs<br><br>Basic UDI-DI code: 697065458MD3143EFS | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |
| Specimen collection swabs<br><br>Basic UDI-DI code: 697065458MD3143FFU | Class I devices placed on the market in sterile condition | N/A | DD 2041633-1 #0197 |

Table 2: Devices covered by this letter and for which the NB is NOT 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 |
|---|---|---|---|
| NA | NA | NA | NA |

**Confirmation Letter Revision History**

| Date | NB internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2024/04/28 | 326013431 | Initial issue |