Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Anhui JN Medical Device Co.,Ltd.
Caicun Town, Jing County, Xuancheng City,
242525 Anhui,
P.R. China

Contact

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

Date December 15, 2023

Notified Body Confirmation Letter
Reference. : 244556658

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:

Anhui JN Medical Device Co.,Ltd.
Caicun Town, Jing County, Xuancheng City,
242525 Anhui,
P.R. China
SRN Number: CN-MF-000031311

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

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Germany

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Board of Management

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Nuremberg HRB 26013
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Chairman of the
Supervisory Board

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

Herbert Zhong
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**
Infusion sets for Single use Model: A Basic UDI-DI: 6972765750398PE	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Infusion sets for Single use Model: A2 Basic UDI-DI: 6972765750404EG	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Infusion sets for Single use Model: A3 Basic UDI-DI: 6972765750411ED	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Infusion sets for Single use Model: A4	Class IIa	N/A	Certificate # DD 60140171 0001 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
Basic UDI-DI: 6972765750428EW			
Infusion sets for Single use Model: A5 Basic UDI-DI: 6972765750435ET	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Infusion sets for Single use Model: A6 Basic UDI-DI: 6972765750442EQ	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Infusion sets for Single use Model: A7 Basic UDI-DI: 6972765750459F9	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Infusion sets for Single use Model: A8 Basic UDI-DI: 6972765750466F6	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Infusion sets for Single use Model: A9 Basic UDI-DI: 6972765750473F3	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Infusion sets for Single use Model: A10 Basic UDI-DI: 6972765750480EY	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Infusion sets for Single use Model: A11 Basic UDI-DI: 6972765750497FH	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Infusion sets for Single use	Class IIa	N/A	Certificate # DD 60140171 0001 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
Model: A12 Basic UDI-DI: 6972765750503EK			
Scalp Vein Sets for Single Use Model: 28G Basic UDI-DI: 6972765750077EP	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Scalp Vein Sets for Single Use Model: 27G Basic UDI-DI: 6972765750084EL	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Scalp Vein Sets for Single Use Model: 26G Basic UDI-DI: 6972765750091EH	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Scalp Vein Sets for Single Use Model: 25G Basic UDI-DI: 6972765750107E7	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Scalp Vein Sets for Single Use Model: 24G Basic UDI-DI: 6972765750114E4	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Scalp Vein Sets for Single Use Model: 23G Basic UDI-DI: 6972765750121DZ	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Scalp Vein Sets for Single Use Model: 22G Basic UDI-DI: 6972765750138EJ	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Scalp Vein Sets for Single Use	Class IIa	N/A	Certificate #

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
Model: 21G Basic UDI-DI: 6972765750145EF			DD 60140171 0001 NB #0197
Scalp Vein Sets for Single Use Model: 20G Basic UDI-DI: 6972765750152EC	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Scalp Vein Sets for Single Use Model: 19G Basic UDI-DI: 6972765750169EV	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Scalp Vein Sets for Single Use Model: 18G Basic UDI-DI: 6972765750176ES	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Transfusion Sets for Single Use Model: B1 Basic UDI-DI: 6972765750374EY	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Transfusion Sets for Single Use Model: B2 Basic UDI-DI: 6972765750381EV	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Syringes for Single Use Model: 1ml Basic UDI-DI: 6972765750527EZ	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Syringes for Single Use Model: 2ml Basic UDI-DI: 6972765750534EW	Class IIa	N/A	Certificate # DD 60140171 0001 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
Sterile Hypodermic Syringes for Single Use Model: 3ml Basic UDI-DI: 6972765750541ET	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Syringes for Single Use Model: 5ml Basic UDI-DI: 6972765750558FC	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Syringes for Single Use Model: 10ml Basic UDI-DI: 6972765750565F9	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Syringes for Single Use Model: 20ml Basic UDI-DI: 6972765750572F6	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Syringes for Single Use Model: 30ml Basic UDI-DI: 6972765750589FP	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Syringes for Single Use Model: 50ml Basic UDI-DI: 6972765750596FL	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model: 30G Basic UDI-DI:	Class IIa	N/A	Certificate # DD 60140171 0001 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
6972765750183EP			
Sterile Hypodermic Needles for Single Use Model: 29G Basic UDI-DI: 6972765750190EL	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model: 28G Basic UDI-DI: 6972765750206EA	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model:27G Basic UDI-DI: 6972765750213ET	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model:26G Basic UDI-DI: 6972765750220E4	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model: 25G Basic UDI-DI: 6972765750237EM	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model: 24G Basic UDI-DI: 6972765750244EJ	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model: 23G	Class IIa	N/A	Certificate # DD 60140171 0001 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
Basic UDI-DI: 6972765750251EF			
Sterile Hypodermic Needles for Single Use Model: 22G Basic UDI-DI: 6972765750268EY	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model: 21G Basic UDI-DI: 6972765750275EV	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model: 20G Basic UDI-DI: 6972765750282ES	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model: 19G Basic UDI-DI: 6972765750299FB	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Sterile Hypodermic Needles for Single Use Model: 18G Basic UDI-DI: 6972765750305ED	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Disposable insulin Syringes Model: 0.3ml U-100 Basic UDI-DI: 69727657598895J5	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Disposable insulin Syringes Model: 0.5ml U-100 Basic UDI-DI:	Class IIa	N/A	Certificate # DD 60140171 0001 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
69727657598 96J2			
Disposable insulin Syringes Model: 1.0ml U-100 Basic UDI-DI: 6972765759902H4	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Disposable insulin Syringes Model: 0.5ml U-40 Basic UDI-DI: 6972765759919HM	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Disposable insulin Syringes Model: 1.0ml U-40 Basic UDI-DI: 6972765759926HJ	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Disposable insulin Syringes Model: 2.0ml U-40 Basic UDI-DI: 6972765759933HF	Class IIa	N/A	Certificate # DD 60140171 0001 NB #0197
Irrigation Syringes Model: A Basic UDI-DI: 6972765758868HN	Class Is	N/A	Certificate # DD 60140171 0001 NB #0197
Irrigation Syringes Model: B Basic UDI-DI: 6972765758837HB	Class Is	N/A	Certificate # DD 60140171 0001 NB #0197
Irrigation Syringes Model: C Basic UDI-DI: 6972765758899HZ	Class Is	N/A	Certificate # DD 60140171 0001 NB #0197
Disposable Transfer Sets Model: T-A Basic UDI-DI: 6972765759384H2	Class Is	N/A	Certificate # DD 60140171 0001 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 Transfer Sets Model: T-B Basic UDI-DI: 6972765759414GJ	Class Is	N/A	Certificate # DD 60140171 0001 NB #0197
Disposable Transfer Sets Model: T-C Basic UDI-DI: 6972765759421GF	Class Is	N/A	Certificate # DD 60140171 0001 NB #0197
Disposable Transfer Sets Model: T-D Basic UDI-DI: 6972765759438GY	Class Is	N/A	Certificate # DD 60140171 0001 NB #0197
Disposable Transfer Sets Model: T-E Basic UDI-DI: 6972765759445GV	Class Is	N/A	Certificate # DD 60140171 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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-12-15	244556658	Initial issue

Anhui JN Medical Device Co.,Ltd.
安徽江南医疗器械股份有限公司

Manufacturer's Declaration

In relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Anhui JN Medical Device Co.,Ltd.
Manufacturer address and contact details	Caicun Town Jing County Xuancheng City,Anhui,China
Single Registration Number (SRN) (if available)	CN-MF-000031311

Authorised Representative name (if applicable)	Prolinx GmbH
Authorised Representative address and contact details	Brehmstr.56,40239,Duesseldorf,Germany
Single Registration Number (SRN) (if available)	DE-AR-000005129

Notified body name (if applicable)	☑ See attached schedule
Notified body number (if applicable)	☑ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☑ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☑ See attached schedule
End date of extended validity/transition period	☑ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Choose applicable statements:

☐Expired *before* 20 March 2023:

☐Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

☐A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

☐A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☑Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☑Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☑A QMS in accordance with Article 10(9) MDR is in place.
☐A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name

Anhui JN Medical Device Co.,Ltd.

Location & Date

Caicun Town Jing County Xuancheng City,Anhui,China

2023/10/23

Signature, Print Name, Title

General manage: *Xing weiqi*

Contact Details (at least email)

Email：jnmedical@126.com;xcjn001@163.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Infusion Sets for Single Use	DD 601401710001	2023-10-18	TÜV Rheinland LGA Products GmbH,0197	TÜV Rheinland LGA Products GmbH,0197	2028-12-31	
Scalp Vein Sets for Single Use	DD 601401710001	2023-10-18	TÜV Rheinland LGA Products GmbH,0197	TÜV Rheinland LGA Products GmbH,0197	2028-12-31	
Transfusion Sets for Single Use	DD 601401710001	2023-10-18	TÜV Rheinland LGA Products GmbH,0197	TÜV Rheinland LGA Products GmbH,0197	2028-12-31	
Sterile Hypodermic Syringes for Single Use	DD 601401710001	2023-10-18	TÜV Rheinland LGA Products GmbH,0197	TÜV Rheinland LGA Products GmbH,0197	2028-12-31	
Sterile Hypodermic Needles for Single Use	DD 601401710001	2023-10-18	TÜV Rheinland LGA Products GmbH,0197	TÜV Rheinland LGA Products GmbH,0197	2028-12-31	
Infusion Sets with precision Filters for Single Use	DD 601401710001	2023-10-18	TÜV Rheinland LGA Products GmbH,0197	TÜV Rheinland LGA Products GmbH,0197	2028-12-31	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Disposable insulin Syringes	DD 601401710001	2023-10-18	TÜV Rheinland LGA Products GmbH,0197	TÜV Rheinland LGA Products GmbH,0197	2028-12-31	
Irrigation Syringes	DD 601401710001	2023-10-18	TÜV Rheinland LGA Products GmbH,0197	TÜV Rheinland LGA Products GmbH,0197	2028-12-31	
Disposable Transfer Sets	DD 601401710001	2023-10-18	TÜV Rheinland LGA Products GmbH,0197	TÜV Rheinland LGA Products GmbH,0197	2028-12-31	

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60140171 0001

Report No.: 15062350 009

Manufacturer:
Anhui JN Medical Device Co., Ltd.
Caicun Town, Jing County
Xuancheng City
242525 Anhui
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60135530 0001

Expiry Date: 2023-10-18

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.

Effective Date: 2019-06-19

Date: 2019-06-19

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH
TÜVRheinland
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.

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60140171 0001
Report No.: 15062350 009

Manufacturer:
Anhui JN Medical Device Co., Ltd.
Caicun Town, Jing County
Xuancheng City
242525 Anhui
China

Products:

Infusion Sets for Single Use, Scalp Vein Sets for Single Use, Transfusion Sets for Single Use, Sterile Hypodermic Syringes for Single Use, Sterile Hypodermic Needles for Single Use, Infusion Sets with Precision Filters for Single Use, Disposable Insulin Syringes;

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Irrigation Syringes, Disposable Transfer Sets

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

Date: 2019-06-19

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