

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

Registration No.: DD 60149237 0001

Report No.: 15064112 011

Manufacturer: Yangzhou Medline Industry Co., Ltd.
No. 108, Jinshan Road
Economic Development Zone
Yangzhou
225009 Jiangsu
P.R. China

Products: Medical Devices

(see attachment for scope and additional site included)

Replaces Approval, Registration No.: DD 60134897 0001

Expiry Date: 2023-10-11

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: 2020-05-11

Date: 2020-05-11

Notified Body



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev.0

**Attachment to
Certificate**

Registration No.: DD 60149237 0001
Report No.: 15064112 011

Manufacturer: Yangzhou Medline Industry Co., Ltd.
No. 108, Jinshan Road
Economic Development Zone
Yangzhou
225009 Jiangsu
P.R. China

Products:

- Disposable Insulin Syringes
- Disposable Syringes
- Three-way Stopcocks
- Auto-disable Syringes
- Disposable Infusion Sets
- Hypodermic Needles
- IV Catheters
- Surgical Blades
- Feeding Tubes
- Stomach Tubes
- Suction Catheters
- Disposable Safety Auto-disable Syringes
- Disposable Safety Hypodermic Needles
- Scalp Vein Sets
- Disposable Vacuum Blood Collection Needles
- Disposable Safety Vacuum Blood Collection Needles
- Disposable Safety Scalp Vein Sets
- Retractable Safety Syringes (No Gap Type)
- Safety Vacuum Blood Collection Needles (Pen Type)

Date: 2020-05-11

Notified Body

Herbert Zhong



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60149237 0001
Report No.: 15064112 011

Manufacturer: Yangzhou Medline Industry Co., Ltd.
No. 108, Jinshan Road
Economic Development Zone
Yangzhou
225009 Jiangsu
P.R. China

Products:

- Disposable Syringes with Safety Needles
- Disposable Safety Insulin Syringes
- Safety Lancets
- Disposable Surgical Procedure Kits (Masks, Medical Gauze, applicator, Medical tape, Disposable syringe, Infusion sets)

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Disposable Urine Bags
- Surgical Brushes
- Filter Needles for single use
- Pre-filled Flush Syringes
- Disposable Feeding Syringes

Site included:

Yangzhou Medline Industry Co., Ltd
No. 1, Huafa Road, Development Zone, Yangzhou, Jiangsu
225000, China

Notified Body

Date: 2020-05-11

Herbert Zhong



TÜV Rheinland LGA Products GmbH • 51105 Köln

Yangzhou Medline Industry Co., Ltd.
No.108 Jinshan Road, Economic Development Zone, Yangzhou,
225009, Jiangsu
P.R. China

Contact

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Date October 26, 2023

Notified Body Confirmation Letter

Reference. : 244546581

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:

Yangzhou Medline Industry Co., Ltd.
No.108 Jinshan Road, Economic Development Zone, Yangzhou,
225009, Jiangsu
P.R. China
SRN Number: CN-MF-000026644

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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VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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
Disposable Insulin Syringe Model: U-100: 0.3mL, 0.5mL, 1mL Basic UDI-DI code: 69418452MDLINSUE	Class IIa	Disposable Insulin Syringes Type: 0.3mL, 0.5mL, 1mL	Certificate #: DD 60149237 0001 NB#:0197
Disposable Insulin Syringe Model: U-40: 0.3mL, 0.5mL, 1mL Basic UDI-DI code: 69418452MDLINS-40M6	Class IIa	Disposable Insulin Syringes Type: 0.3mL, 0.5mL, 1mL	Certificate #: DD 60149237 0001 NB#:0197
Disposable Safety Insulin Syringe Model: U-100: 0.3mL, 0.5mL, 1mL Basic UDI-DI code: 69418452MDLSINS37	Class IIa	Disposable Safety Insulin Syringes Type:gauge size:29,ang 30 nominal capacity was 0.5mL, 1mL	Certificate #: DD 60149237 0001 NB#:0197 Note: model 0.3mL is not covered by MDD certificate.
Disposable Safety Insulin Syringe Model: U-40: 0.3mL, 0.5mL, 1mL	Class IIa	Disposable Safety Insulin Syringes Type:gauge size:29,ang 30	Certificate #: DD 60149237 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 code: 69418452MDLSINS-40EH		nominal capacity was 0.5mL, 1mL	Note: model 0.3mL is not covered by MDD certificate.
Disposable Syringe Model: 0.3mL, 0.5mL, 1mL, 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL, 50mL, 60mL, 100mL with needle Basic UDI-DI code: 69418452MDLDSWNZW	Class IIa	Disposable Syringes Type: 1mL, 2mL, 3mL, 5mL, 10mL, 20mL, 50mL, 60mL	Certificate #: DD 60149237 0001 NB#:0197 Note: models : 0.3mL, 0.5mL, 2.5mL, 100mL are not covered by MDD certificate.
Auto-disable Syringe Model: 0.3mL, 0.5mL, 1mL, 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL with needle Basic UDI-DI code: 69418452MDLATSWNBZ	Class IIa	Auto-disable Syringes Type: 0.5mL, 1mL, 2mL, 3mL, 5mL, 10mL, 20mL	Certificate #: DD 60149237 0001 NB#:0197 Note: models : 0.3mL, 2.5mL, are not covered by MDD certificate.
Safety Auto-disable Syringe Model: 0.3mL, 0.5mL, 1mL, 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL with needle Basic UDI-DI code: 69418452MDLSATSWNXR	Class IIa	Disposable Safety Auto-disable Syringes Type: 1/2/3/5/10/20	Certificate #: DD 60149237 0001 NB#:0197 Note: models : 0.3mL,0.5mL,2.5mL, are not covered by MDD certificate.
Disposable Syringe with Safety Needle Model: 0.3mL, 0.5mL, 1mL, 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL Basic UDI-DI code: 69418452MDLSWSN5J	Class IIa	Disposable Syringe with Safety Needles Syringe: 1mL, 2mL, 3mL, 5mL, 10mL, 20mL,50mL,60mL Safety Needle:16G,18G,19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G,28G,29G,30G	Certificate #: DD 60149237 0001 NB#:0197 Note: models : 0.3mL,0.5mL,2.5mL, are not covered by MDD certificate.
Retractable Safety Syringe Model: 0.3mL, 0.5mL, 1mL, 2mL, 2.5mL, 3mL, 5mL, 10mL, 20mL with needle Basic UDI-DI code: 69418452MDLRSSWNHM	Class IIa	Retractable Safety Syringes (no Gap Type) Type:1mL, 2mL, 3mL, 5mL, 10mL, 20mL	Certificate #: DD 60149237 0001 NB#:0197 Note: models : 0.3mL,0.5mL,2.5mL, are not covered by MDD certificate.
Three-way Stopcock Model: without extension tube 69418452MDLTSUY	Class I devices placed on the market in sterile condition	Three-way Stopcock Type: Blue,with male lock adaptor,with extension tube	Certificate #: DD 60149237 0001 NB#:0197
Three-way Stopcock Model: with extension tube	Class I devices placed on the	Three-way Stopcock Type: Blue,with male lock adaptor,with extension tube	Certificate #: DD 60149237 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 code: 69418452MDLTSWT5V	market in sterile condition		
Scalp Vein Set Model: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G Basic UDI-DI code: 69418452MDLSVSWQ	Class IIa	Scalp Vein Sets Type: 18G-27G"	Certificate #: DD 60149237 0001 NB#:0197
Safety Scalp Vein Set Model: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G Basic UDI-DI code: 69418452MDLSSVS5H	Class IIa	Disposable Safety Scalp Vein Sets Type: 18G-27G	Certificate #: DD 60149237 0001 NB#:0197
Vacuum Blood Collection Needle Model: pen type, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G Without Holder Basic UDI-DI code: 69418452MDLVBCNPTUJ	Class IIa	Disposable Vacuum Blood Collection Needles Type, 18G-27G	Certificate #: DD 60149237 0001 NB#:0197
Vacuum Blood Collection Needle Model: pen type, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G With Holder Basic UDI-DI code: 69418452MDLVBCSPTVB	Class IIa	Disposable Vacuum Blood Collection Needles Type, 18G-27G	Certificate #: DD 60149237 0001 NB#:0197
Vacuum Blood Collection Needle Model: butterfly type, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G Without Holder Basic UDI-DI code: 69418452MDLVBCNBTT8	Class IIa	Disposable Vacuum Blood Collection Needles Type, 18G-27G	Certificate #: DD 60149237 0001 NB#:0197
Vacuum Blood Collection Needle Model: butterfly type, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G With Holder Basic UDI-DI code: 69418452MDLVBCSBTTZ	Class IIa	Disposable Vacuum Blood Collection Needles Type, 18G-27G	Certificate #: DD 60149237 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
Safety Vacuum Blood Collection Needle Model: safety needle type, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G Without Holder Basic UDI-DI code: 69418452MDLSVBCNPTMV	Class IIa	Safety Vacuum Blood Collection Needles(Pen Type) types:18G-27G, Pen Type: 21G, 22G, 23G	Certificate #: DD 60149237 0001 NB#:0197
Vacuum Blood Collection Needle Model: butterfly type, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G With Holder Basic UDI-DI code: 69418452MDLSVBCSPTNN	Class IIa	Disposable Vacuum Blood Collection Needles Type, 18G-27G	Certificate #: DD 60149237 0001 NB#:0197
Safety Vacuum Blood Collection Needle Model: butterfly type, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G Without Holder Basic UDI-DI code: 69418452MDLSVBCNBTLK	Class IIa	Safety Vacuum Blood Collection Needles(Pen Type) types:18G-27G, Pen Type: 21G, 22G, 23G	Certificate #: DD 60149237 0001 NB#:0197
Safety Vacuum Blood Collection Needle Model: butterfly type, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G With Holder Basic UDI-DI code: 69418452MDLSVBCSBTMC	Class IIa	Disposable Safety Vacuum Blood Collection Needles types:18G-27G	Certificate #: DD 60149237 0001 NB#:0197
Hypodermic Needle Model: 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G Basic UDI-DI code: 69418452MDLHNTJ	Class IIa	Hypodermic Needle Type: 16G-30G	Certificate #: DD 60149237 0001 NB#:0197 Note: models : 31G, 32G, 33G, are not covered by MDD certificate.
Safety Needle Model: 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G Basic UDI-DI code: 69418452MDLSNUK	Class IIa	Disposable Safety Hypodermic Needles Type: 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G	Certificate #: DD 60149237 0001 NB#:0197 Note: models : 16G, 17G, 31G, 32G, 33G, are not covered by MDD 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
Dispensing Needle Model: Blunt type, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G Basic UDI-DI code: 69418452MDLDNBXTJ	Class I devices placed on the market in sterile condition	Filter Needles for single use Type:16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	Certificate #: DD 60149237 0001 NB#:0197
Dispensing Needle Model: Filter type, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G Basic UDI-DI code: 69418452MDLDNFTXW	Class I devices placed on the market in sterile condition	Filter Needles for single use Type:16G,18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	Certificate #: DD 60149237 0001 NB#:0197
Disposable Surgical Procedure Kits Model I: Forcep, Clamp, Medical pad, Scissors, Medical gauze Basic UDI-DI code: 69418452MDLSPK1ZU	Class I devices placed on the market in sterile condition	Disposable Surgical Operational Kits Type:A: Forceps, Clamps, Medical pad, applicators, Medical gauzes; B:Disposable syringes,infusion sets, Medical pad, cotton applicator/swabs,wound bands,examination gloves,adhesive tapes,masks,bedsheets,Medical gauzes	Certificate #: DD 60149237 0001 NB#:0197
Disposable Surgical Procedure Kits Model II: Forcep, Clamp, Medical pad, Scissors, Medical gauze, Applicator, Cotton swab, Examination gloves, Adhesive tape, Mask Basic UDI-DI code: 69418452MDLSPK2ZW	Class I devices placed on the market in sterile condition	Disposable Surgical Operational Kits Type:A: Forceps, Clamps, Medical pad, applicators, Medical gauzes; B:Disposable syringes,infusion sets, Medical pad, cotton applicator/swabs,wound bands,examination gloves,adhesive tapes,masks,bedsheets,Medical gauzes	Certificate #: DD 60149237 0001 NB#:0197
Pre-filled Syringe Model: Without needle, 0.3mL, 0.5mL, 1mL, 2mL, 2.25mL, 2.5mL, 3mL, 5mL, 10mL, 20mL Basic UDI-DI code: 69418452MDLPSWONGT	Class IIa	Pre-filled Flush Syringes Type: 3mL, 5mL, 10mL, 20mL	Certificate #: DD 60149237 0001 NB#:0197 Note: models : 0.3mL, 0.5mL, 1mL, 2mL, 2.25mL, 2.5mL, are not covered by MDD certificate.
Pre-filled Syringe	Class IIa	Pre-filled Flush Syringes Type: 3mL, 5mL, 10mL, 20mL	Certificate #: DD 60149237 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
Model: With needle, 0.3mL, 0.5mL, 1mL, 2mL, 2.25mL, 2.5mL, 3mL, 5mL, 10mL, 20mL Basic UDI-DI code: 69418452MDLPSWN4M			NB#:0197 Note: models : 0.3mL, 0.5mL, 1mL, 2mL, 2.25mL, 2.5mL, are not covered by MDD certificate.
Disposable Feeding Syringe Model: 1mL, 2mL, 3mL, 5mL, 10mL, 20mL, 30mL, 50mL, 60mL Basic UDI-DI code: 69418452MDLFSTN	Class I devices placed on the market in sterile condition	N/A	Certificate #: DD 60149237 0001 NB#:0197 Note: model 30mL is not covered by MDD certificate.
Disposable Urine Bag Model: 100mL, 200mL, 500mL, 1000mL, 1500mL, 2000mL Basic UDI-DI code: 69418452MDLUBTZ	Class I devices placed on the market in sterile condition	N/A	Certificate #: DD 60149237 0001 NB#:0197 Note: models : 100mL, 200mL, are not covered by MDD certificate.
Surgical Brush Model: A, B Basic UDI-DI code: 69418452MDLSBTT	Class I devices placed on the market in sterile condition	N/A	Certificate #: DD 60149237 0001 NB#:0197
Infusion Set Model: Adult use; Pediatric Use with needle Basic UDI-DI code: 69418452MDLINSWNDF	Class IIa	Disposable Infusion Set Type:inlet,non-inlet	Certificate #: DD 60149237 0001 NB#:0197
IV Catheter Model: butterfly type Basic UDI-DI code: 69418452MDLIVCBTB4	Class IIa	IV Catheter Type: 16G,18G,20G,22G,24G	Certificate #: DD 60149237 0001 NB#:0197
IV Catheter Model: pen type Basic UDI-DI code: 69418452MDLIVCPTCE	Class IIa	IV Catheter Type: 16G,18G,20G,22G,24G	Certificate #: DD 60149237 0001 NB#:0197
IV Catheter Model: with injection port Basic UDI-DI code: 69418452MDLIVCWIPWM	Class IIa	IV Catheter Type: 16G,18G,20G,22G,24G	Certificate #: DD 60149237 0001 NB#: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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/10/26	244546581	Initial issue