Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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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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 Ttpe: 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: 69418452MDLDNBTXJ**	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 TypeI: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 TypeI: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 <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
2023/10/26	244546581	Initial issue