EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:	**YANGZHOU MEDLINE INDUSTRY CO., LTD. NO. 108, JINSHAN ROAD, ECONOMIC DEVELOPMENT ZONE, YANGZHOU, CHINA**
EU Representative	**Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537, Hamburg, Germany**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / the medical device: / le dispositif médical: / il dispositivo medico:	**Terumo Syringe with / without Needle** **Detailed size: see attachment**
der Klasse: / of class: / de la classe: / di classe:	**IIa**

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC / selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll". /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il "rapporto di ispezione finale" del prodotto.

Konformitätsbewertungsverfahren: / Conformity assessment procedure: / Procédure d'évaluation de la conformité: / Procedura di valutazione della conformità:	**Directive 93/42/EEC Annex V**
Registrier-Nr.: / Registration No.: / N°d'enregistrement: / Numero di registrazione:	DD 60149237 0001
Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:	**TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Deutschland CE 0197**

9 December 2021 JiangSu Yangzhou

Ort, Datum / Place, date / Lieu, date / Luogo, data

QC Manager TanWei

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

Common Name: Disposable Syringe							
No	Brand Name	New product code	needle	size	tip	needle	needle length
1	Terumo Syringe with/without Needle	MDSS01SE	w/o	1ML	slip		
2		MDSS03LE	w/o	3ML	Lock		
3		MDSS03SE	w/o	3ML	slip		
4		MDSS05LE	w/o	5ML	Lock		
5		MDSS05SE	w/o	5ML	slip		
6		MDSS10LE	w/o	10ML	Lock		
7		MDSS10SE	w/o	10ML	slip		
8		MDSS20LE	w/o	20ML	Lock		
9		MDSS20ESE	w/o	20ML	Eccentric slip		
10		MDSS60ESE	w/o	60ML	Eccentric slip		
11		MDSS01S2516E	w/n	1ML	slip	25	16
12		MDSS01S2613E	w/n	1ML	slip	26	13
13		MDSS01S2713E	w/n	1ML	slip	27	13
14		MDSS03L2238E	w/n	3ML	Lock	22	38
15		MDSS03L2325E	w/n	3ML	Lock	23	25
16		MDSS03L2332E	w/n	3ML	Lock	23	32
17		MDSS03L2425E	w/n	3ML	Lock	24	25
18		MDSS03L2516E	w/n	3ML	Lock	25	16
19		MDSS05L2325E	w/n	5ML	Lock	23	25
20		MDSS05L2332E	w/n	5ML	Lock	23	32
21		MDSS05S2138E	w/n	5ML	slip	21	38
22		MDSS05S2332E	w/n	5ML	slip	23	32
23		MDSS05S2238E	w/n	5ML	slip	22	38
24		MDSS10L2138E	w/n	10ML	Lock	21	38
25		MDSS10L2238E	w/n	10ML	Lock	22	38
26		MDSS10S2038E	w/n	10ML	slip	20	38
27		MDSS10S2138E	w/n	10ML	slip	21	38
28		MDSS10S2238E	w/n	10ML	slip	22	38
29		MDSS03S2116E	w/n	3ML	slip	21	16
30		MDSS03S2125E	w/n	3ML	slip	21	25
31		MDSS03S2138E	w/n	3ML	slip	21	38
32		MDSS03S2238E	w/n	3ML	slip	22	38
33		MDSS03S2325E	w/n	3ML	slip	23	25
34		MDSS03S2332E	w/n	3ML	slip	23	32
35		MDSS03S2516E	w/n	3ML	slip	25	16
36		MDSS10ESE	w/o	10ML	Eccentric slip		
37		MDSS05L2125E	w/n	5ML	Lock	21	25
38		MDSS05L2232E	w/n	5ML	Lock	22	32
39		MDSS10L2025E	w/n	10ML	Lock	20	25

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

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

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

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.

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

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

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

Herbert Zhong

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

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)

Notified Body

Date: 2020-05-11

Herbert Zhong

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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 Zertifizierungsstelle

YANGZHOU MEDLINE INDUSTRY CO., LTD.
Tel: 0086-514-87525616; Fax: 0086-514-87525631
Web: www.chinamedline.com; Email: president@cnmedical.net; sales3@cnmedical.net

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	Yangzhou Medline Industry Co., Ltd.
Manufacturer address and contact details	No. 108, Jinshan Road, Economic Development Zone, Yangzhou, China. Tel:0086-514-87525616, Fax:0086-514-87525631, president@cnmedical.net
Single Registration Number (SRN) (if available)	CN-MF-000026644

Authorised Representative name (if applicable)	Shanghai International Holding Corp. GmbH(Europe)
Authorised Representative address and contact details	Eiffestraße, 80 20537 Hamburg, Germany. shholding@hotmail.com Tel: +49 40 2513175
Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	□ See attached schedule
Notified body number (if applicable)	

[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.

	□ 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

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:

  ☒ 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.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

[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

- ☐ 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:

Yangzhou Medline Industry Co., Ltd.

Yangzhou, 2023.09.04

Tan wei, QC Manager

tanwei@chinamedline.com

YANGZHOU MEDLINE INDUSTRY CO., LTD.

Tel: 0086-514-87525616; Fax: 0086-514-87525631

Web: www.chinamedline.com; Email: president@cnmedical.net; sales3@cnmedical.net

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)
Terumo Syringe with/ without Needle	DD 60149237 0001	2023-10-11	TÜV Rheinland LGA Products GmbH CE 0197	TÜV Rheinland LGA Products GmbH 245791710	31/12/2028	Not applicable

[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)

YANGZHOU MEDLINE INDUSTRY CO., LTD.

Tel: 0086-514-87525616; Fax: 0086-514-87525631

Web: www.chinamedline.com; Email: president@cnmedical.net; sales3@cnmedical.net