EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: /	**Yangzhou Medline Industry Co., Ltd.** **No.108 Jinshan Road, Economic Development Zone, Yangzhou, 225009 Jiangsu, P.R. China** **SRN: CN-MF-000026644**
Registered trade name or mark:/	**Terumo Syringe with needle**
EC Authorized Representative:/	**Shanghai International Trading Corp. GmbH(Hamburg)** **Eiffestrasse 80, 20537 Hamburg, Germany** **SRN: DE-AR-000000001**

We declare under our sole responsibility that

Name of the medical device: /	**Terumo Syringe with needle**
Product code:/	**Model: 1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 60ml** **EMDN code: A020102 Infusion and Irrigation syringes, single-use**
Intended purpose：/	**It is used for both injection and aspiration of fluids, and intravenous, subcutaneous and intramuscular route;**
Basic UDI-DI:/	**69418452MDLDSWNZW**
CS reference: /	**NONE**
of class: / According to annex VIII of Regulation (EU) 2017/745 /	**Rule 6, Class IIa**
Conformity assessment procedure:	**MDR Annex IX Chapter I, section 2 and 3 and Chapter III**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2, 90431 Nürnberg Germany**
NB Identification number :	**CE0197**
Certificate No.: /	**HZ 2110300-1**

Meets the provisions of the Regulation (EU) 2017/745 and other relevant Union legislation which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

2025.08.06	QIJIANZHONG
Ort, Datum / Place, date / Lieu, date / Luogo, data	Name und Funktion / Name and function / Nom et fonction / Nome e funzione

ATTACHMENT

Common Name: Disposable Syringe							
No	Brand Name	New product code	**needle**	**size**	**tip**	**needle**	**needle length**
1	Terumo Syringe with Needle	MDSS01S2516E	w/n	1ML	Slip	25	16
2		MDSS01S2613E	w/n	1ML	Slip	26	13
3		MDSS01S2713E	w/n	1ML	Slip	27	13
4		MDSS03S2116E	w/n	3ML	Slip	21	16
5		MDSS03S2125E	w/n	3ML	Slip	21	25
6		MDSS03S2138E	w/n	3ML	Slip	21	38
7		MDSS03S2238E	w/n	3ML	Slip	22	38
8		MDSS03S2325E	w/n	3ML	Slip	23	25
9		MDSS03S2332E	w/n	3ML	Slip	23	32
10		MDSS03S2516E	w/n	3ML	Slip	25	16
11		MDSS03L2238E	w/n	3ML	Lock	22	38
12		MDSS03L2325E	w/n	3ML	Lock	23	25
13		MDSS03L2332E	w/n	3ML	Lock	23	32
14		MDSS03L2425E	w/n	3ML	Lock	24	25
15		MDSS03L2516E	w/n	3ML	Lock	25	16
16		MDSS05L2125E	w/n	5ML	Lock	21	25
17		MDSS05L2232E	w/n	5ML	Lock	22	32
18		MDSS05L2325E	w/n	5ML	Lock	23	25
19		MDSS05L2332E	w/n	5ML	Lock	23	32
20		MDSS05S2138E	w/n	5ML	Slip	21	38
21		MDSS05S2332E	w/n	5ML	Slip	23	32
22		MDSS05S2238E	w/n	5ML	Slip	22	38
23		MDSS10L2025E	w/n	10ML	Lock	20	25
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

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: /	**Yangzhou Medline Industry Co., Ltd.** **No.108 Jinshan Road, Economic Development Zone, Yangzhou, 225009 Jiangsu, P.R. China** **SRN: CN-MF-000026644**
Registered trade name or mark:/	**Terumo Syringe without needle**
EC Authorized Representative:/	**Shanghai International Trading Corp. GmbH(Hamburg)** **Eiffestrasse 80, 20537 Hamburg, Germany** **SRN: DE-AR-000000001**

We declare under our sole responsibility that

Name of the medical device: /	**Terumo Syringe without needle**
Product code:/	**Model: 1ml, 3ml, 5ml, 10ml, 20ml, 30ml, 60ml** **EMDN code: A020102 Infusion and Irrigation syringes, single-use**
Intended purpose：/	**It is used for both injection and aspiration of fluids, and intravenous, subcutaneous and intramuscular route;**
Basic UDI-DI:/	**69418452MDLDSWONCP**
CS reference: /	**NONE**
of class: / According to annex VIII of Regulation (EU) 2017/745 /	**Rule 2, Class Is**
Conformity assessment procedure:	**MDR Annex IX Chapter I, section 2 and 3 and Chapter III**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2, 90431 Nürnberg Germany**
NB Identification number :	**CE0197**
Certificate No.: /	**HZ 2110300-1**

Meets the provisions of the Regulation (EU) 2017/745 and other relevant Union legislation which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

2025.08.06	QIJIANZHONG
Ort, Datum / Place, date / Lieu, date / Luogo, data	Name und Funktion / Name and function / Nom et fonction / Nome e funzione

ATTACHMENT

Common Name: Disposable Syringe							
No	Brand Name	New product code	**needle**	**size**	**tip**	**needle**	**needle length**
1	Terumo Syringe without Needle	MDSS01LE	w/o	1ML	Lock		
2		MDSS01SE	w/o	1ML	Slip		
3		MDSS03LE	w/o	3ML	Lock		
4		MDSS03SE	w/o	3ML	Slip		
5		MDSS05LE	w/o	5ML	Lock		
6		MDSS05SE	w/o	5ML	Slip		
7		MDSS10LE	w/o	10ML	Lock		
8		MDSS10SE	w/o	10ML	Slip		
9		MDSS10ESE	w/o	10ML	Eccentric slip		
10		MDSS20LE	w/o	20M	Lock		
11		MDSS20ESE	w/o	20ML	Eccentric slip		
12		MDSS60ESE	w/o	60ML	Eccentric slip		

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2110300-1
Manufacturer:	Yangzhou Medline Industry Co., Ltd. No. 108, Jinshan Road Economic Development Zone Yangzhou 225009 Jiangsu P.R. China
EUDAMED Single Registration No.:	CN-MF-000026644
Products:	Products of class I, sterile: A020102-INFUSION AND IRRIGATION SYRINGES, SINGLE-USE - Disposable Syringes - Auto-disable Syringes - Safety Auto-disable Syringes - Disposable Safety Syringes - Retractable Safety Syringes A070103-INFUSION LINES ADAPTERS AND CONNECTORS - Three-way Stopcocks A019001-BLUNT NEEDLES - Dispensing Needles A020108-ENTERAL FEEDING SYRINGES - Disposable Feeding Syringes A060301-COLLECTION BAGS AND OTHER CONTAINERS

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	244489770-200
Effective date:	2024-08-01
Expiry date:	2029-07-31
Issue date:	2024-08-01

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

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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Precisely Right.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2110300-1
Manufacturer:	Yangzhou Medline Industry Co., Ltd. No. 108, Jinshan Road Economic Development Zone Yangzhou 225009 Jiangsu P.R. China
EUDAMED Single Registration No.:	CN-MF-000026644
	FOR DRAINAGES AND FISTULAS, SINGLE USE - Disposable Urine Bags A030101-INFUSION CONTROLLERS - Infusion Sets A1101-SAMPLE COLLECTION NEUTRAL SWABS - Specimen Collection Swabs V9099-VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES - OTHER - Surgical Brushes T020604-MEDICAL USE FACE MASKS, TYPE II AND IIR - Disposable Medical Masks The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions Products of class IIa: A020106-INSULIN SYRINGES, SINGLE-USE - Disposable Insulin Syringes - Disposable Safety Insulin Syringes A020102-INFUSION AND IRRIGATION SYRINGES, SINGLE-USE - Disposable Syringes
Report No.:	244489770-200
Effective date:	2024-08-01
Expiry date:	2029-07-31
Issue date:	2024-08-01

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

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Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2110300-1
Manufacturer:	Yangzhou Medline Industry Co., Ltd. No. 108, Jinshan Road Economic Development Zone Yangzhou 225009 Jiangsu P.R. China
EUDAMED Single Registration No.:	CN-MF-000026644

- Auto-disable Syringes
- Safety Auto-disable Syringes
- Disposable Safety Syringes
- Disposable Syringe with safety needles
- Retractable Safety Syringes

A010102-BUTTERFLY NEEDLES
- Scalp Vein Sets
- Safety Scalp Vein Sets

A010105-NEEDLES FOR COLLECTION UNDER VACUUM
- Vacuum Blood Collection Needles
- Safety Vacuum Blood Collection Needles

A010101-HYPODERMIC NEEDLES
- Hypodermic Needles
- Safety Needles

A030101-INFUSION CONTROLLERS
- Infusion Sets

C010101-PERIPHERAL I.V. CATHETERS
- IV Catheters

Report No.:	244489770-200
Effective date:	2024-08-01
Expiry date:	2029-07-31
Issue date:	2024-08-01

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EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2110300-1
Manufacturer:	Yangzhou Medline Industry Co., Ltd. No. 108, Jinshan Road Economic Development Zone Yangzhou 225009 Jiangsu P.R. China
EUDAMED Single Registration No.:	CN-MF-000026644
Authorized representative(s):	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-08-01

Report No.:	244489770-200
Effective date:	2024-08-01
Expiry date:	2029-07-31
Issue date:	2024-08-01

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