

# 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 2002969-1

Manufacturer: **Terumo (Philippines) Corporation**  
124 East Main Avenue, Laguna Technopark,  
Binan, Laguna 4024  
Philippines

EUDAMED Single  
Registration No.: PH-MF-000001794

Products: Products of class IIa:  
  
A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE  
C010101 - PERIPHERAL I.V. CATHETERS  
A010101 - HYPODERMIC NEEDLES

Authorised  
representative(s): Terumo Europe N.V  
Interleuvenlaan 40 B-3001, Leuven Belgium

Certificate history		
Revision:	Description:	Issue date:
0	Initial Certification	2023-11-06

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.: 176131510-20

Effective date: 2023-11-06

Expiry date: 2028-11-05

Issue date: 2023-11-06



  
Ning N. C. Chang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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



## EU DECLARATION OF CONFORMITY

We,

Terumo (Philippines) Corporation  
124 East Main Avenue, Laguna Technopark  
Binan, Laguna, Philippines  
SRN: PH-MF-000001794

being the manufacturer of:

### **Terumo Syringe with Needle Terumo Syringe without Needle**

Intended purpose: The device is intended for use in the aspiration and injection of fluids for medical purposes such as injecting medication solution into tissues such as intracutaneous tissue, a subcutaneous tissue, a muscle, etc. or body cavities, or collecting blood or body fluid.

Basic UDI-DI:

Syringe with Needle: 48060175SSNY5  
Syringe without Needle: 48060175SSB6

Related product codes: See Appendix A

declare that the above product of Class IIa is in conformity with the applicable requirements of the Regulation (EU) 2017/745 of 5 April 2017 on Medical Devices and has been subject to the conformity assessment procedure laid down in Article 52.6 of the Regulation, relating to the "Conformity assessment based on a quality management system and on assessment of Technical Documentation" set out in Annex IX Chapter I, Section 2 and 3. The requirements of Annex IX, Chapter III relating to the "Administrative Provisions" is also fulfilled.  
[refer to the scope of applicable requirement as stated in the certificate]

Authorized Representative:

Terumo Europe N.V  
Interleuvenlaan 40, B-3001  
Leuven, Belgium  
SRN: BE-AR-000001433

Compliance has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH  
Tillystraße 2, 90431, Nürnberg, Germany  
Certificate No.: HZ 2002969-1  
Issue date: 2023-11-06  
Expiry date: 2028-11-05  
NB Number: NB 0197

### **TERUMO (PHILIPPINES) CORPORATION**

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Tel. No. (049) 541-2111 Fax No. (049) 541-2121

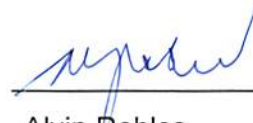
Rev. 2  
PH-PQB-SS011

This EU Declaration of Conformity is under the sole responsibility of Terumo (Philippines) Corporation.

Philippines, 2025-04-03

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Place, date of issuance



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Alvin Robles  
QA General Manager

For and on behalf of  
Terumo (Philippines) Corporation

## APPENDIX A: LIST OF PRODUCT CODES

Product Code	Syringe Size	Needle Size
SS+01TM	1 cc/mL Luer Tip	N/A
SS+01T2516M	1 cc/mL Luer Tip	25G x 5/8" (16mm)
SS+01T2713M	1 cc/mL Luer Tip	27G x 1/2" (13mm)
SS+03LM	3 cc/mL Luer Lock Tip	N/A
SS+03L2038M	3 cc/mL Luer Lock Tip	20G x 1 1/2" (38mm)
SS+03L2125M	3 cc/mL Luer Lock Tip	21G x 1" (25mm)
SS+03L2138M	3 cc/mL Luer Lock Tip	21G x 1 1/2" (38mm)
SS+03L2225M	3 cc/mL Luer Lock Tip	22G x 1" (25mm)
SS+03L2232M	3 cc/mL Luer Lock Tip	22G x 1 1/4" (32mm)
SS+03L2238M	3 cc/mL Luer Lock Tip	22G x 1 1/2" (38mm)
SS+03L2325M	3 cc/mL Luer Lock Tip	23G x 1" (25mm)
SS+03L2525M	3 cc/mL Luer Lock Tip	25G x 1" (25mm)
SS+05LM	5 cc/mL Luer Lock Tip	N/A
SS+05L2125M	5 cc/mL Luer Lock Tip	21G x 1" (25mm)
SS+05L2138M	5 cc/mL Luer Lock Tip	21G x 1 1/2" (38mm)
SS+05L2225M	5 cc/mL Luer Lock Tip	22G x 1" (25mm)
SS+05L2232M	5 cc/mL Luer Lock Tip	22G x 1 1/4" (32mm)
SS+05L2238M	5 cc/mL Luer Lock Tip	22G x 1 1/2" (38mm)
SS+10ESM	10 cc/mL Eccentric Tip	N/A
SS+10LM	10 cc/mL Luer Lock Tip	N/A
SS+10L2132M	10 cc/mL Luer Lock Tip	21G x 1 1/4" (32mm)
SS+10L2138M	10 cc/mL Luer Lock Tip	21G x 1 1/2" (38mm)
SS+10L2232M	10 cc/mL Luer Lock Tip	22G x 1 1/4" (32mm)
SS+10L2238M	10 cc/mL Luer Lock Tip	22G x 1 1/2" (38mm)
SS+20ESM	20 cc/mL Eccentric Tip	N/A
SS+20LM	20 cc/mL Luer Lock Tip	N/A

Product Code	Syringe Size	Needle Size
SS+01T	1 cc/mL Luer Tip	N/A
SS+01T2516	1 cc/mL Luer Tip	25G x 5/8" (16mm)
SS+01T2613	1 cc/mL Luer Tip	26G x 1/2" (13mm)
SS+01T2713	1 cc/mL Luer Tip	27G x 1/2" (13mm)
SS+03S	3 cc/mL Luer Tip	N/A
SS+03L	3 cc/mL Luer Lock Tip	N/A
SS+03L2138	3 cc/mL Luer Lock Tip	21G x 1 1/2" (38mm)
SS+03L2325	3 cc/mL Luer Lock Tip	23G x 1" (25mm)
SS+03L2332	3 cc/mL Luer Lock Tip	23G x 1 1/4" (32mm)
SS+03L2516	3 cc/mL Luer Lock Tip	25G x 5/8" (16mm)
SS+05S	5 cc/mL Luer Tip	N/A
SS+05L	5 cc/mL Luer Lock Tip	N/A
SS+05L2025	5 cc/mL Luer Lock Tip	20G x 1" (25mm)
SS+05L2038	5 cc/mL Luer Lock Tip	20G x 1 1/2" (38mm)
SS+05L2125	5 cc/mL Luer Lock Tip	21G x 1" (25mm)
SS+05L2138	5 cc/mL Luer Lock Tip	21G x 1 1/2" (38mm)
SS+05L2232	5 cc/mL Luer Lock Tip	22G x 1 1/4" (32mm)
SS+05L2238	5 cc/mL Luer Lock Tip	22G x 1 1/2" (38mm)
SS+05L2325	5 cc/mL Luer Lock Tip	23G x 1" (25mm)
SS+05L2332	5 cc/mL Luer Lock Tip	23G x 1 1/4" (32mm)
SS+10S	10 cc/mL Luer Tip	N/A
SS+10ES	10 cc/mL Eccentric Tip	N/A
SS+10L	10 cc/mL Luer Lock Tip	N/A
SS+10L2125	10 cc/mL Luer Lock Tip	21G x 1" (25mm)
SS+10L2138	10 cc/mL Luer Lock Tip	21G x 1 1/2" (38mm)
SS+10L2325	10 cc/mL Luer Lock Tip	23G x 1" (25mm)
SS+20L	20 cc/mL Luer Lock Tip	N/A
SS+20ES	20 cc/mL Eccentric Tip	N/A
SS+60C	60 cc/mL Catheter Tip	N/A
SS+60L	60 cc/mL Luer Lock Tip	N/A

Product Code	Syringe Size	Needle Size
SS+03L1	3 cc/mL Luer Lock Tip	N/A
SS+05L1U	5 cc/mL Luer Lock Tip	N/A
SS+10L1	10 cc/mL Luer Lock Tip	N/A
SS+30L1	30 cc/mL Luer Lock Tip	N/A

Product Code	Syringe Size	Needle Size
SS+01T1	1 cc/mL Luer Tip	N/A
SS+01T25161	1 cc/mL Luer Tip	25G x 5/8" (16mm)
SS+01T26131	1 cc/mL Luer Tip	26G x 1/2" (13mm)
SS+03L21161	3 cc/mL Luer Lock Tip	21G x 5/8" (16mm)
SS+03L2116A1	3 cc/mL Luer Lock Tip	21G x 5/8" (16mm)
SS+03L21381	3 cc/mL Luer Lock Tip	21G x 1 1/2" (38mm)
SS+03L2138A1	3 cc/mL Luer Lock Tip	21G x 1 1/2" (38mm)
SS+03L22381	3 cc/mL Luer Lock Tip	22G x 1 1/2" (38mm)
SS+03L23251	3 cc/mL Luer Lock Tip	23G x 1" (25mm)
SS+05S21381	5 cc/mL Luer Tip	21G x 1 1/2" (38mm)
SS+05S23321	5 cc/mL Luer Tip	23G x 1 1/4" (32mm)
SS+10ES1	10 cc/mL Eccentrip Tip	N/A
SS+10S20381	10 cc/mL Luer Tip	20G x 1 1/2" (38mm)
SS+10S21381	10 cc/mL Luer Tip	21G x 1 1/2" (38mm)
SS+10S22381	10 cc/mL Luer Tip	22G x 1 1/2" (38mm)
SS+20ES1	20 cc/mL Eccentrip Tip	N/A
SS+20L1	20 cc/mL Luer Lock Tip	N/A
SS+30ES1	30 cc/mL Eccentrip Tip	N/A
SS+30L1MP	30 cc/mL Luer Lock Tip	N/A
SS+50ES1	50 cc/mL Eccentrip Tip	N/A
SS+50L1	50 cc/mL Luer Lock Tip	N/A
SS+50C1	50 cc/mL Catheter Tip	N/A

Product Code	Syringe Size	Needle Size
SS+01T6	1 cc/mL Luer Tip	N/A