



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

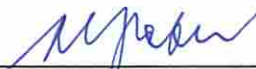
TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HZ 2002969-1
Issue date: 2023-11-06
Expiry date: 2028-11-05

Rev. 1
PH-PQB-SS011

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

Philippines, 2024-01-22

Place, date of issuance



Alvin Robles
Management Representative

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