

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60147309 0001

Report No.: 12031274 008

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

Products: See attachments for products and sites included
Replaces Approval, Registration No.: DD 60108472 0001

Expiry Date: 2024-05-26

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: 2020-05-01

Date: 2020-05-01



Notified Body


Takashi Matsuda

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 60147309 0001
Report No.: 12031274 008

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

Manufacturing site included:

Terumo (Philippines) Corporation
128 East Main Avenue, Laguna Technopark, Binan, Laguna,
4024, Philippines

Aspects of manufacturing concerned with securing and
maintaining sterile conditions:

- Urinary Drainage Bags

Sterilization (Electron Beam Irradiation) site included:

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

Date: 2020-05-01



Notified Body

T. Matsuda

Takashi Matsuda

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60147309 0001
Report No.: 12031274 008

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

Products included:

- Syringes with Needles
- Intravenous Catheters
- Safety Needles
- Syringes with Safety Needles
- Syringes without Needles
- Hypodermic Needles

Aspects of manufacturing concerned with securing and maintaining sterile conditions:

- Urinary Drainage Bags
- Syringes for Oral / Enteral

Date: 2020-05-01



Notified Body

T. Matsuda

Takashi Matsuda



TERUMO (PHILIPPINES) CORPORATION

124 East Main Ave., Laguna Technopark, Biñan, Laguna, Philippines
Tel. No. (049) 541-2111 • Fax No. (049) 541-2121

EC Declaration of Conformity

We,

Terumo (Philippines) Corporation
124 East Main Avenue, Laguna Technopark
Binan, Laguna, Philippines

whose single Authorized Representative:

Terumo Europe N.V
Interleuvenlaan 40, 3001 Leuven, Belgium

Being the manufacturer, herewith declare that the products:

Terumo® Syringe with Needle
Terumo® Syringe without Needle
(with attached product codes)

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

C E0197

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: DD 60147309 0001

Issue date: 2020 – 05 – 01

Expiry date: 2024 – 05 – 26

following the procedure relating to the "EC Declaration of Conformity" set out in Annex VII, combined with the provisions set out in Annex V "Production Quality Assurance" of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

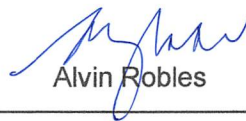
The above mentioned declaration of conformity is exclusively under the responsibility of

Terumo (Philippines) Corporation

Philippines,

05/17/21

Place, date of issuance



Alvin Robles

Management Representative

**Declaration of Conformity
Terumo Syringe with Needle
List of Product Codes**

Terumo Syringe with Needle

Volume mL	Product Description	Needle Size Gauge x Length	Product Codes	Lot Number
1	Syringe with Needle	23G x 1"	SS+01T2325	TBD
1		25G x 5/8"	SS+01T2516	140116D
1		25G x 5/8"	SS+01T2516M	140213D
1		25G x 5/8"	SS+01T25161	131222D
1		25G x 5/8"	SS+01T25166	140203D
1		26G x 3/8"	SS+01T2609	130907D
1		26G x 1/2"	SS+01T2613	140207S
1		26G x 1/2"	SS+01T26131	130905D
1		26G x 1/2"	SS+01T26136	140208D
1		27G x 1/2"	SS+01T2713	140208D
1		27G x 1/2"	SS+01T2713M	130713D
1		Insulin Syringe	26G x 1/2"	SS+01N2613
1	26G x 1/2"		SS+01H26131	130904D
1	25G x 5/8"		SS+01H25161	130802D
3	Syringe with Needle – Lock Tip	20G x 1"	SS+03L2025	TBD
3		20G x 1"	SS+03L2025M	100205F
3		20G x 1 1/4"	SS+03L2032M	130511F
3		20G x 1 1/2"	SS+03L2038M	130612F
3		21G x 5/8"	SS+03L21161	210325K
3		21G x 1"	SS+03L2125	121017F
3		21G x 1"	SS+03L2125M	131203F
3		21G x 1 1/4"	SS+03L2132M	131226F
3		21G x 1 1/2"	SS+03L2138	131203F
3		21G x 1 1/2"	SS+03L2138M	131203F
3		21G x 1 1/2"	SS+03L21386	141117F
3		21G x 1 1/2"	SS+03L21381	TBD
3		22G x 1"	SS+03L2225	TBD
3		22G x 1"	SS+03L2225M	130710F
3		22G x 1 1/4"	SS+03L2232M	140209M
3		22G x 1 1/2"	SS+03L2238	131206F
3		22G x 1 1/2"	SS+03L2238M	131217F
3		22G x 1 1/2"	SS+03L22381	TBD
3		23G x 1"	SS+03L2325	140212K
3		23G x 1"	SS+03L2325M	140213P
3	23G X 1"	SS+03L23251	TBD	

**Declaration of Conformity
Terumo Syringe with Needle
List of Product Codes**

Volume mL	Product Description	Needle Size Gauge x Length	Product Codes	Lot Number
3		23G x 1 1/4"	SS+03L2332	140207P
3		23G x 1 1/2"	SS+03L2338	121016F
3		24G x 1"	SS+03L2425	131207F
3		25G x 1"	SS+03L2525	TBD
3		25G x 1"	SS+03L2525M	TBD
3		25G x 5/8"	SS+03L2516	140206F
3		25G x 5/8"	SS+03L2516M	130803F
3	Syringe with Needle – Luer Tip	21G x 1 1/2"	SS+03S2138M	131010A
3		22G x 3/4"	SS+03S2219	070831F
3		22G x 1 1/2"	SS+03S2238	130918A
3		23G x 1"	SS+03S2325	140206A
3		23G x 1 1/4"	SS+03S2332	131112F
3		24G x 1"	SS+03S2425	130825A
3		25G x 5/8"	SS+03S2516	131116A
3	Syringe with Needle – Lock Tip	21G x 5/8"	SS+03L2116A1	TBD
3		21G x 1 1/2"	SS+03L2138A1	TBD
5		20G x 1"	SS+05L2025	TBD
5		20G x 1 1/2"	SS+05L2038	TBD
5		20G x 1 1/4"	SS+05L2032M	130801C
5		21G x 1"	SS+05L2125	130923C
5		21G x 1"	SS+05L2125M	131018C
5		21G x 1 1/4"	SS+05L2132M	140211R
5		21G x 1 1/2"	SS+05L2138	131016C
5		21G x 1 1/2"	SS+05L2138M	130615C
5		21G x 1 1/2"	SS+05L21386	141229C
5		22G x 1"	SS+05L2225	TBD
5		22G x 1"	SS+05L2225M	131120C
5		22G x 1 1/2"	SS+05L2238	140207C
5		22G x 1 1/2"	SS+05L22386	TBD
5		22G x 1 1/2"	SS+05L2238M	130911C
5		22G x 1 1/4"	SS+05L2232	131130C
5		22G x 1 1/4"	SS+05L2232M	140210R
5		23G x 1"	SS+05L2325	140130C
5		23G x 1 1/4"	SS+05L2332	140206C
5	Syringe with Needle – Luer Tip	21G x 1"	SS+05S2125	TBD
5		21G x 1 1/2"	SS+05S2138	130726C

**Declaration of Conformity
Terumo Syringe with Needle
List of Product Codes**

Volume mL	Product Description	Needle Size Gauge x Length	Product Codes	Lot Number
5		21G x 1 1/2"	SS+05S2138M	131216C
5		21G x 1 1/2"	SS+05S21381	140214C
5		22G x 1 1/2"	SS+05S2238	130810C
5		22G x 1 1/2"	SS+05S22381	140216C
5		23G x 1"	SS+05S2325	130811C
5		23G x 1 1/4"	SS+05S2332	131113C
5		23G x 1 1/4"	SS+05S23321	140221C
10	Syringe with Needle – Lock Tip	20G x 1"	SS+10L2025	140213L
10		20G x 1 1/4"	SS+10L2032M	130922L
10		21G x 1"	SS+10L2125	131108E
10		21G x 1 1/4"	SS+10L2132M	140214L
10		21G x 1 1/2"	SS+10L2138	140123N
10		21G x 1 1/2"	SS+10L2138M	131204L
10		22G x 1 1/4"	SS+10L2232	TBD
10		22G x 1 1/4"	SS+10L2232M	140213L
10		22G x 1 1/2"	SS+10L2238	131203L
10		22G x 1 1/2"	SS+10L2238M	131204L
10		23G x 1"	SS+10L2325	140211L
10	Syringe with Needle – Luer Tip	20G x 1 1/2"	SS+10S20381	130607E
10		21G x 1"	SS+10S2125	080104E
10		21G x 1 1/2"	SS+10S2138	140210E
10		21G x 1 1/2"	SS+10S21386	160515E
10		21G x 1 1/2"	SS+10S2138M	130702E
10		21G x 1 1/2"	SS+10S21381	130720E
10		22G x 1 1/4"	SS+10S2232	121013E
10		22G x 1 1/2"	SS+10S2238	131215E
10		22G x 1 1/2"	SS+10S22381	130805E
10	23G x 1"	SS+10S2325	140119E	

Terumo Syringe without Needle

Volume mL	Product Description	Product Codes	Lot Number
1	Syringe without Needle	SS+01T	140204S
1		SS+01TM	130206S

Declaration of Conformity
Terumo Syringe with Needle
List of Product Codes

Volume mL	Product Description	Product Codes	Lot Number
1		SS+01T6	130731D
1		SS+01T1	130815D
1	Insulin Syringe without Needle	SS+01H1	130731D
3		SS+03L	130704K
3	Syringe without Needle – Lock Tip	SS+03L1	140122K
3		SS+03LM	131018A
3		SS+03L6	140206P
3	Syringe without Needle – Luer Tip	SS+03S	131012F
3		SS+03S6	140206F
5		SS+05L	140127V
5		SS+05L1	131203E
5	Syringe without Needle – Lock Tip	SS+05L6	130918C
5		SS+05LM	130731C
5		SS+05L1U	170325R
5		SS+05S	130721V
5	Syringe without Needle – Luer Tip	SS+05S1	140207V
5		SS+05S6	140213V
10		SS+10L	140206N
10	Syringe without Needle – Lock Tip	SS+10L1	131105N
10		SS+10L6	131203N
10		SS+10LM	140206N
10	Syringe without Needle – Luer Tip	SS+10S	130621E
10		SS+10S6	140207W
10	Syringe without Needle – Eccentric Luer Tip	SS+10ES	140207E
10		SS+10ESM	131009W
10		SS+10ES1	140208E
20		SS+20L	131227B
20	Syringe without Needle – Lock Tip	SS+20L1	140206B
20		SS+20LM	140209B
20	Syringe without Needle – Luer Tip	SS+20S	130513B
20		SS+20SM	110609B
20		SS+20ES	140206B
20	Syringe without Needle – Eccentric Luer Tip	SS+20ES6	131130B
20		SS+20ESM	140204B
20		SS+20ES1	140203B
30	Syringe without Needle – Lock Tip	SS+30L1	131105G
30	Syringe without Needle – Luer Lock Tip	SS+30L1MP	190213G

Declaration of Conformity
Terumo Syringe with Needle
List of Product Codes

Volume mL	Product Description	Product Codes	Lot Number
30	Syringe without Needle - Eccentric Luer Tip	SS+30ES1	190226G
50	Syringe without Needle – Eccentric Luer Tip	SS+50ES1	140206H
50	Syringe without Needle – Catheter Tip	SS+50C1	140124H
50	Syringe without Needle – Lock Tip	SS+50L1	140623H
60	Syringe without Needle – Catheter Tip	SS+60C	140107H
60		SS+60CM	131026H
60	Syringe without Needle – Lock Tip	SS+60L	150903H

Note: TBD = To Be Determined