

SERINGUES TROIS PIECES (TPC)

1. Renseignements administratifs concernant l'entreprise		<i>Date de mise à jour : Avril 2019</i>
1.1	Nom : TERUMO France SAS	
1.2	Adresse complète : Bâtiment Renaissance 3 Rond-Point des Saules 78280 Guyancourt	Tel : 08 00 90 50 42 Fax : 01 30 96 12 90 e-mail : service.client@terumo-europe.com Site internet : www.terumo-europe.com
1.3	Coordonnées du correspondant matériorigilance : Aurélie FLAMENT	Tel : 06 89 66 59 73 Fax : 01 30 96 12 90 e-mail : aurelie.flament@terumo-europe.com
2. Informations sur le dispositif ou équipement		
2.1	<u>Dénomination commune</u> : selon la nomenclature d'Europharmat® Seringue	
2.2	<u>Dénomination commerciale</u> : Seringue trois pièces	
2.3	<u>Code nomenclature</u> : Code GMDN : 35904 Code CLADIMED : K54BB03	
2.4	<u>Code LPP*</u> : Non applicable * « liste des produits et prestations remboursables » inscrits sur la liste prévue à l'article L 165-1	
2.5	Classe du DM : IIa Directive de l'UE applicable : 93/42/CE Selon Annexe n° V Numéro de l'organisme notifié : CE 0197 Date de première mise sur le marché dans l'UE : Avant 1998 Fabricant du DM : Terumo Philippines Corporation (TPC) 124 East Main Avenue - Laguna Technopark, Binan - Philippines	
2.6	<u>Descriptif du dispositif (avec photo, schéma, dimensions, volume, ...)</u> : Seringue trois pièces à usage unique, stérile et apyrogène. La seringue est destinée : - à l'injection de liquides immédiatement après le remplissage dans le corps humain, - à l'aspiration de liquides ou au prélèvement de sang ou d'autres liquides organiques. Ne contient pas de composants en PVC ou en latex de caoutchouc naturel.	



2.7 Références Catalogue :

Tableau des références

Référence	Volume	Graduation (ml)	Embout
8SS01T1	1 ml	0,01	Luer Slip, centré
8SS03L1	3 ml	0,1	Luer Lock, centré
8SS10ES1	10 ml	0,2	Luer Slip, excentré
8SS20ES1	20 ml	1	Luer Slip, excentré
8SS20L1	20 ml	1	Luer Lock, centré
8SS30ES1	30 ml	1	Luer Slip, excentré
8SS30L1MP	30 ml	1	Luer Lock, centré
8SS50ES1	50 ml	1	Luer Slip, excentré
8SS50L1	50 ml	1	Luer Lock, centré
8SS50C1	50 ml	1	Embout cathéter

Référence	Unités / boîte	Unités / carton	Poids du carton	Dimensions carton (mm)
8SS01T1	1 ml	1800	7,50 kg	430 x 418 x 306
8SS03L1	3 ml	1800	7,50 kg	640 x 385 x 262
8SS10ES1	10 ml	1200	11,00 kg	546 x 454 x 428
8SS20ES1	20 ml	600	10,15 kg	570 x 400 x 366
8SS20L1	20 ml	200	6,20 kg	552 x 386 x 238
8SS30ES1	30 ml	200	6,32 kg	552 x 386 x 238
8SS30L1MP	30 ml	600	10,15 kg	570 x 400 x 366
8SS50ES1	50 ml	100	5,10 kg	466 x 312 x 268
8SS50L1	50 ml	100	5,10 kg	466 x 312 x 268
8SS50C1	50 ml	100	5,40 kg	466 x 312 x 268

Conditionnement/Emballages :

UCD (Unité de commande): 100, 50 ou 25 seringues selon la référence (voir tableau ci-dessus)

CDT (Multiple de l'UCD): Quantité variable selon la référence (voir tableau ci-dessus)

QML (Quantité minimale de livraison) : Le carton

Code à barres : EAN 128

Etiquetage : Voir annexe

2.8 Composition du dispositif et Accessoires : pour chaque élément ou composant, précisé :

<u>Dispositif</u>	<u>Eléments</u>	<u>Matériaux</u>
Seringue	Corps	Polypropylène
	Piston	Polypropylène Polystyrène (pour seringue 1 ml uniquement)
	Joint	Elastomère thermoplastique
	Lubrifiant	Huile de silicone (conforme à la pharmacopée européenne)

Pour les composants susceptibles d'entrer en contact avec le patient et/ou les produits administrés, précisions complémentaires :

- Absence de Latex
- Absence de produit d'origine animale ou biologique
- Absence de PVC/Phtalates

Toutes mentions jugées utiles pour les précautions d'utilisation :

- Vérifier l'intégrité du protecteur individuel de stérilité (blister) avant utilisation
- Strict usage unique, détruire après usage selon les procédures locales d'élimination des déchets de soins

2.9 Domaine - Indications :

Domaine d'utilisation (selon liste Europharmat) : Injection ou prélèvement

Indications (selon liste Europharmat) : Injection manuelle ou pousse seringue

(Se conférer à la validation des seringues compatibles pour les pousses-seringues faite par le fabricant de ces derniers)



Dossier d'information Euro Pharmat

DISPOSITIF MEDICAL

3. Procédé de stérilisation :	
	DM stérile : OUI Mode de stérilisation du dispositif : Par faisceau d'électrons, SAL 10 ⁻⁶
4. Conditions de conservation et de stockage	
	Conditions normales de conservation & de stockage Précautions particulières : Ne pas utiliser si l'emballage est endommagé. Ne pas réutiliser. Éliminer de façon sécuritaire après une utilisation unique afin d'éviter tout risque d'infection. Durée de la validité du produit : 5 ans Présence d'indicateurs de température s'il y a lieu : Non
5. Sécurité d'utilisation	
5.1	Sécurité technique : Voir annexe
5.2	Sécurité biologique (s'il y a lieu) : Non applicable
6. Conseils d'utilisation	
6.1	Mode d'emploi : Voir annexe
6.2	Indications : Voir annexe
6.3	Précautions d'emploi : Voir Annexe
6.4	Contre- Indications : Voir Annexe
7. Informations complémentaires sur le produit	
	<u>Bibliographie, rapport d'essais cliniques, ou d'études pharmaco-économiques, amélioration du service rendu : recommandations particulières d'utilisation (restrictions de prise en charge, plateau technique, qualification de l'opérateur, etc) ... :</u>
8. Liste des annexes au dossier (s'il y a lieu)	
	<ul style="list-style-type: none">✓ Mode d'emploi, boîte, étiquetage blister (Annexe 1)✓ Certificat de marquage CE (Annexe 2)✓ Déclaration de conformité (Annexe 3)
9. Images (s'il y a lieu)	
	Format gif, jpeg, png

ANNEXE 1

Terumo syringes with/without needle

Representative labelling

Representative labels are shown for each packaging level for Terumo syringes with/without needle

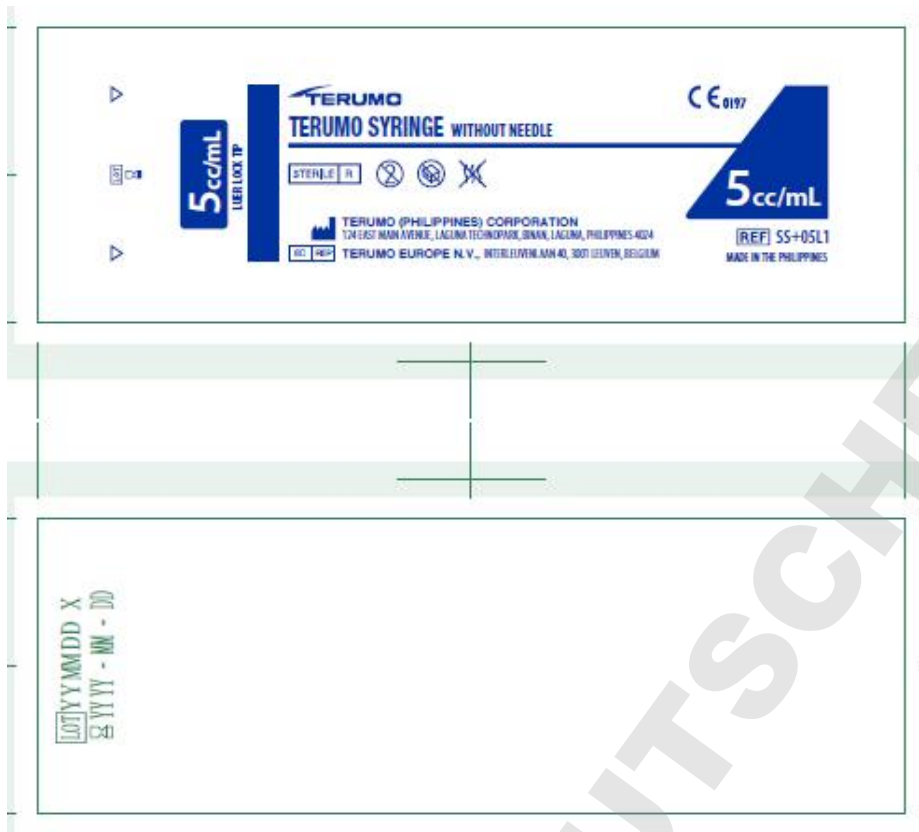
Unit box label



Shipping carton label



Individual packaging



ANNEXE 2

DOMINIQUE DEUTSCHER SAS

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

Registration No.: DD 60108472 0001

Report No.: 12031276 001

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 60083914 0001

Expiry Date: 2021-02-11

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: 2016-02-12

Date: 2016-02-12



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 60108472 0001
Report No.: 12031276 001

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

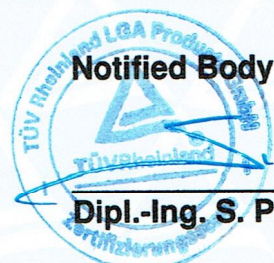
Products included:

- 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: 2016-02-12



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60108472 0001
Report No.: 12031276 001

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
- Intravenous Catheter
- Safety Needles
- Syringes with Safety Needles

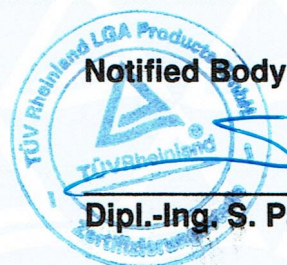
**Aspects of manufacturing concerned with securing and
maintaining sterile conditions:**

- Urinary Drainage Bags

Sterilization (Electron Beam Irradiation) site included:

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

Date: 2016-02-12



ANNEXE 3

DOMINIQUE DUTSCHER SAS



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 the 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

CE 0197

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 60108472 0001
Issue date: 2016 – 02 – 12
Expiry date: 2021 – 02 – 11

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,

06/04/18

Place, date of issuance

Alvin Robles

Alvin Robles

Management Representative

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

Terumo Syringe with Needle

Volume mL	Product Description	Needle Size Gauge x Length	Product Codes	Lot Number
		23G x 1"	SS+01T2325	TBD
		25G x 1"	SS+01T2525	TBD
		25G x 5/8"	SS+01T2516	140116D
			SS+01T2516M	140213D
			SS+01T25161	131222D
			SS+01T25166	140203D
		26G x 3/8"	SS+01T2609	130907D
		26G x 1/2"	SS+01T2613	140207S
			SS+01T26131	130905D
			SS+01T26136	140208D
	27G x 1/2"	SS+01T2713	140208D	
		SS+01T2713M	130713D	
	Insulin Syringe	25G x 5/8"	SS+01N2516	TBD
		26G x 1/2"	SS+01N2613	101014D
		26G x 1/2"	SS+01H26131	130904D
		25G x 5/8"	SS+01H25161	130802D
2.5	Syringe with Needle – Luer Tip	21G x 5/8"	SS+02S21161	140918Y
		21G x 1"	SS+02S21251	140820Y
		21G x 1 1/2"	SS+02S21381	140916Y
		22G x 1 1/2"	SS+02S22381	140915Y
		23G x 1"	SS+02S23251	140708Y
		23G x 1 1/4"	SS+02S23321	140809Y
		25G x 5/8"	SS+02S25161	140809Y
3	Syringe with Needle – Lock Tip	20G x 1"	SS+03L2025	TBD
		20G x 1 1/2"	SS+03L2038	TBD
		20G x 1"	SS+03L2025M	100205F
		20G x 1 1/4"	SS+03L2032M	130511F
		20G x 1 1/2"	SS+03L2038M	130612F
		21G x 5/8"	SS+03L2116	TBD
		21G x 1"	SS+03L2125	121017F
			SS+03L2125M	131203F
		21G x 1 1/4"	SS+03L2132M	131226F
		21G x 1 1/2"	SS+03L2138	131203F
			SS+03L2138M	131203F
			SS+03L21386	141117F
		22G x 1"	SS+03L2225	TBD
		22G x 1"	SS+03L2225M	130710F

Declaration of Conformity
Terumo Syringe
List of Product Codes

Volume mL	Product Description	Needle Size Gauge x Length	Product Codes	Lot Number
		22G x 1 1/4"	SS+03L2232	TBD
		22G x 1 1/4"	SS+03L2232M	140209M
		22G x 1 1/2"	SS+03L2238	131206F
			SS+03L2238M	131217F
		23G x 1"	SS+03L2325	140212K
			SS+03L2325M	140213P
		23G x 1 1/4"	SS+03L2332	140207P
		23G x 1 1/2"	SS+03L2338	121016F
		24G x 1"	SS+03L2425	131207F
		25G x 1"	SS+03L2525	TBD
25G x 5/8"	SS+03L2516	140206F		
	SS+03L2516M	130803F		
3	Syringe with Needle – Luer Tip	21G x 5/8"	SS+03S2116	TBD
		21G x 1"	SS+03S2125	TBD
		21G x 1 1/2"	SS+03S2138	131010A
			SS+03S2138M	131010A
		22G x 3/4"	SS+03S2219	070831F
		22G x 1 1/2"	SS+03S2238	130918A
		23G x 1"	SS+03S2325	140206A
		23G x 1 1/4"	SS+03S2332	131112F
		24G x 1"	SS+03S2425	130825A
		23G x 1 1/2"	SS+03S2338	TBD
25G x 5/8"	SS+03S2516	131116A		
5	Syringe with Needle – Lock Tip	20G x 1"	SS+05L2025	TBD
		20G x 1"	SS+05L2025M	091223C
		20G x 1 1/2"	SS+05L2038	TBD
		20G x 1 1/4"	SS+05L2032M	130801C
			SS+05L2125	130923C
		21G x 1"	SS+05L2125M	131018C
			SS+05L2132M	140211R
		21G x 1 1/2"	SS+05L2138	131016C
			SS+05L2138M	130615C
			SS+05L21386	141229C
22G x 1"	SS+05L2225	TBD		
22G x 1"	SS+05L2225M	131120C		
22G x 1 1/4"	SS+05L2232	131130C		

Declaration of Conformity
 Terumo Syringe
 List of Product Codes

Volume mL	Product Description	Needle Size Gauge x Length	Product Codes	Lot Number
	Syringe with Needle – Luer Tip	22G x 1 ½"	SS+05L2232M	140210R
			SS+05L2238	140207C
			SS+05L22386	TBD
			SS+05L2238M	130911C
		23G x 1"	SS+05L2325	140130C
		23G x 1 ¼"	SS+05L2332	140206C
		21G x 1"	SS+05S2125	TBD
		21G x 1 ½"	SS+05S2138	130726C
			SS+05S2138M	131216C
			SS+05S21381	140214C
		22G x 1 ¼"	SS+05S2232	110529C
		22G x 1 ½"	SS+05S2238	130810C
			SS+05S22381	140216C
		23G x 1"	SS+05S2325	130811C
23G x 1 ¼"	SS+05S2332	131113C		
	SS+05S23321	140221C		
10	Syringe with Needle – Lock Tip	20G x 1"	SS+10L2025	140213L
		20G x 1 ¼"	SS+10L2032M	130922L
		20G x 1 ½"	SS+10L2038	061206E
		21G x 1"	SS+10L2125	131108E
10	Syringe with Needle – Lock Tip	21G x 1 ¼"	SS+10L2132M	140214L
		21G x 1 ½"	SS+10L2138	140123N
			SS+10L2138M	131204L
		22G x 1 ¼"	SS+10L2232	TBD
		22G x 1 ¼"	SS+10L2232M	140213L
		22G x 1 ½"	SS+10L2238	131203L
			SS+10L2238M	131204L
	23G x 1"	SS+10L2325	140211L	
	Syringe with Needle – Luer Tip	20G x 1 ½"	SS+10S20381	130607E
		20G x 1"	SS+10S2025	TBD
		20G x 1 ½"	SS+10S2038	TBD
		21G x 1"	SS+10S2125	080104E
		21G x 1 ½"	SS+10S2138	140210E
SS+10S21386			160515E	
SS+10S2138M	130702E			

Declaration of Conformity
Terumo Syringe
List of Product Codes

Volume mL	Product Description	Needle Size Gauge x Length	Product Codes	Lot Number
			SS+10S21381	130720E
		22G x 1 1/4"	SS+10S2232	121013E
		22G x 1 1/2"	SS+10S2238	131215E
			SS+10S22381	130805E
		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
		SS+01TM	130206S
		SS+01T6	130731D
		SS+01T1	130815D
	Insulin Syringe without Needle	SS+01H1	130731D
		SS+01NA	131004S
2.5	Syringe without Needle – Luer Tip	SS+02S1	140215Y
3	Syringe without Needle – Lock Tip	SS+03L	130704K
		SS+03L1	140122K
		SS+03LM	131018A
		SS+03L6	140206P
	Syringe without Needle – Luer Tip	SS+03S	131012F
		SS+03S6	140206F
5	Syringe without Needle – Lock Tip	SS+05L	140127V
		SS+05L1	131203E
		SS+05L6	130918C
		SS+05LM	130731C
		SS+05L1U	170325R
	Syringe without Needle – Luer Tip	SS+05S	130721V
		SS+05S1	140207V
		SS+05S6	140213V
10	Syringe without Needle – Lock Tip	SS+10L	140206N
		SS+10L1	131105N
		SS+10L6	131203N
		SS+10LM	140206N
	Syringe without Needle – Luer Tip	SS+10S	130621E
		SS+10S6	140207W
	Syringe without Needle – Eccentric Luer Tip	SS+10ES	140207E
		SS+10ESM	131009W
		SS+10ES1	140208E

Declaration of Conformity
Terumo Syringe
List of Product Codes

Volume mL	Product Description	Product Codes	Lot Number
20	Syringe without Needle – Lock Tip	SS+20L	131227B
		SS+20L1	140206B
		SS+20LM	140209B
	Syringe without Needle – Luer Tip	SS+20S	130513B
		SS+20SM	110609B
	Syringe without Needle – Eccentric Luer Tip	SS+20ES	140206B
		SS+20ES6	131130B
		SS+20ESM	140204B
SS+20ES1		140203B	
30	Syringe without Needle – Lock Tip	SS+30L1	131105G
	Syringe without Needle – Luer Lock Tip	SS+30L1MP	TBD
	Syringe without Needle - Eccentric Luer Tip	SS+30ES1	TBD
50	Syringe without Needle – Eccentric Luer Tip	SS+50ES1	140206H
	Syringe without Needle – Catheter Tip	SS+50C1	140124H
	Syringe without Needle – Lock Tip	SS+50L1	140623H
60	Syringe without Needle – Catheter Tip	SS+60C	140107H
		SS+60CM	131026H
	Syringe without Needle – Lock Tip	SS+60L	150903H

Note: TBD = To Be Determined