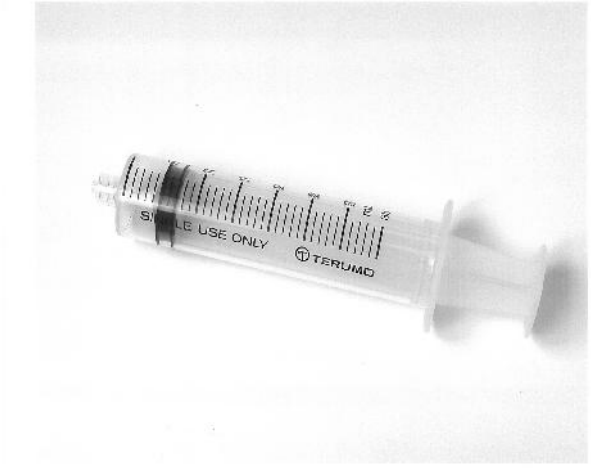
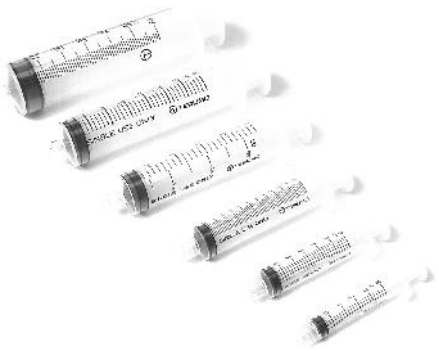
Dossier d'information Euro Pharmat

DISPOSITIF MEDICAL

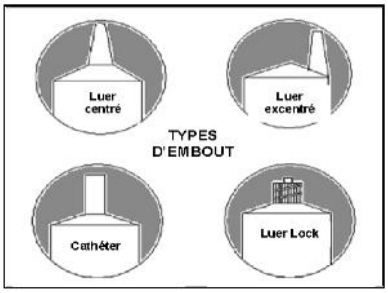
SERINGUES TROIS PIECES LUER LOCK

1. Renseignements administratifs concernant l'entreprise		***Date de mise à jour : Mars 2016***
1.1	**Nom : TERUMO France**	
1.2	**Adresse complète :** **Bât.Renaissance** **3 Rond-Point des Saules** **78284 Guyancourt Cedex**	**Tel: 01 30 96 13 00 Fax : 01 30 43 60 85** **e-mail : terumo.france@terumo-europe.com** **Site internet : www.terumo-europe.com**
1.3	**Coordonnées du correspondant matériovigilance :** **Sara DELANNAY**	**Tel : 01 30 96 13 03** **Fax : 01 30 43 60 85** **e-mail : sara.delannay@terumo-europe.com**
2. Informations sur le dispositif ou équipement		
2.1	**Dénomination commune : selon la nomenclature d'Europharmat® Seringue**	
2.2	**Dénomination commerciale : Seringue trois pièces Luer Lock**	
2.3	**Code nomenclature : Code GMDN : seringue : 35904 et seringue opaque : 45492** **Code CLADIMED : K54BB03**	
2.4	**Code LPP* : 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° I et II** **Numéro de l'organisme notifié : CE 0197 (TÜV Rheinland, Cologne Allemagne)** **Date de première mise sur le marché dans l'UE : Avant 1998** **Fabricant du DM : Terumo Belgique, Terumo Japon et Terumo Philippines**	
2.6	**Descriptif du dispositif (avec photo, schéma, dimensions, volume, …) :** Seringues trois pièces, stériles et non pyrogènes, conformes à la norme NF EN ISO 7886-1 et -2 (seringue/pousse seringue) Elles sont constituées : o d'un corps transparent doté d'un embout luer lock centré et d'un bourrelet d'arrêt interne en haut du corps pour éviter la sortie du piston en bout de course. Graduation conforme à la norme, impression noire ou bleue. o d'un piston muni d'un joint à double lèvre, assurant une étanchéité parfaite l'épaisseur optimale du joint, permet une mobilité du piston sans effort et sans à coup. o L'intérieur du corps de la seringue et le joint sont siliconés.  	

2.7 **Références Catalogue** :

Tableau des références

Références	Description	Nbre Unit/boîte	Nbre unit/carton
1SS02LE1	2.5ml- Luer Lock	100	2400
1SS05LE1	5.0ml- Luer Lock	100	1600
1SS10LE1	10ml- Luer Lock	100	800
1SS30LE1	30ml- Luer Lock	50	400
8SS03L1	3.0ml -Luer lock	100	1800
8SS05L1	5.0ml- Luer lock	100	1200
8SS10L1	10ml- Luer lock	100	1200
8SS20L1	20ml- Luer lock	50	600
8SS30L1	30ml- Luer lock	25	200
8SS50L1	50ml- Luer lock	25	100
8SS50LB1	50ml - opaque	25	100



Conditionnement/Emballages :
UCD (Unité de commande): 100, 50 ou 25 seringues selon le volume
CDT (Multiple de l'UCD): Quantité variable selon le volume voir tableau ci dessus
QML (Quantité minimale de livraison) : Le carton
Code à barres : EAN 128

Descriptif de la référence

POSITIONS	REFERENCES	EXPLICATIONS
1	**1, 2, 8**	Lieu de fabrication : **1**=Japon, **2**=Belgique et **8**=Philippines
2-3	**SS/BS**	Seringue
4-5	**02, 03, 05, 10, 20, 30, 50**	Volume en ml : **02**=2,5 **03**=3ml **05**=5ml **10**=10ml **20**=20ml **30**=30ml **50**=50ml
6	**L**	Luer Lock
7-8	**E1 ou 1**	Stérilisation faisceau électrons

Etiquetage : Voir ANNEXES

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

Dispositif	Eléments	Matériaux
Seringue	Corps	Polypropylène
	Piston	Polypropylène
	Joint	Elastomère thermoplastique,
	Lubrifiant	Huile de silicone

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 (Annexe 7)**
- **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 avant utilisation**
- **Strict usage unique, détruire après usage selon les procédures locales d'élimination des déchets de soins**

Domaine - Indications :

2.9 **Domaine d'utilisation (selon liste Europharmat)** : **Injection**
Indications (selon liste Europharmat) : **Injection manuelle ou pousse seringue selon références**

3. Procédé de stérilisation :	
	DM stérile : **OUI** **Mode de stérilisation du dispositif** : **Références avec un 2 devant = Stérilisé à l'Oxyde d'éthylène, validation du process selon la norme EN ISO 11135-1:2007** **Références avec un 1 ou un 8 devant= Par faisceau d'électrons Selon la norme EN ISO 11137-1:2006/11137-2:2007**
4. Conditions de conservation et de stockage	
	Conditions normales de conservation & de stockage précautions particulières: **- Eviter le stockage à des températures excessives et à l'humidité** 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 1**
5.2	**Sécurité biologique (s'il y a lieu)** : **Non applicable**

6. Conseils d'utilisation	
6.1	**Mode d'emploi** : **Voir annexe 1**
6.2	**Indications** : **Voir annexe 1**
6.3	**Précautions d'emploi** : **Voir Annexe 1**
6.4	**Contre- Indications** : **Voir Annexe 1**
7. Informations complémentaires sur le produit	
	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) … :
8. Liste des annexes au dossier (s'il y a lieu)	
	✓ **Précautions d'emploi sur la boite (Annexe 1)** ✓ **Boîte, Etiquetage blister (Annexes 2, 3)** ✓ **Certificat de marquage CE Japon (Annexe 4)** ✓ **Certificat de marquage CE Philippines (Annexe 5)** ✓ **Déclaration de conformité Japon (Annexe 7)** ✓ **Déclaration de conformité Philippines (Annexe 6)** ✓
9. Images (s'il y a lieu)	
	Format gif, jpeg, png

ANNEXE 1

Précautions d'emploi

STERILE R

Sterilized by electron beam / Stérilisé par faisceau d'électrons / Sterilisiert durch Bestrahlung / Esterilizado por haz de electrones / Sterilizzato a fascio di elettroni / Gesteriliseerd door electron beam / Elektronstrålesteriliserad

For single use only / Strict usage unique / Nur zum einmaligen Gebrauch / Válido para un solo uso / Monouso / Voor éénmalig gebruik / Endast för engångsbruk

LATEX FREE / SANS LATEX / LATEXFREI / SIN LATEX / PRIVO DI LATTICE / LATEX-VRIJ / LATEX FRI

•Sterile and non-pyrogenic in an unopened and undamaged unit package. **<PRECAUTIONS>** •Do not use if the unit package or the product has been damaged or soiled. •Use immediately after opening the unit packaging. •Dispose of safely after single use to avoid risk of infection. •Do not use for high pressure injection of contrast media. **•DO NOT STORE AT EXTREME TEMPERATURES AND HUMIDITY. AVOID DIRECT SUNLIGHT. <INSTRUCTIONS FOR USE>** To open the blister package: peel back the top layer starting from the arrow. (Fig.1)

•Stérile et apyrogène dans un emballage individuel non ouvert et non endommagé. **<PRECAUTIONS>** •Ne pas utiliser si l'emballage individuel ou le produit a été endommagé ou souillé. •Utiliser immédiatement après ouverture de l'emballage individuel. •Eliminer de façon appropriée après usage unique pour éviter le risque d'infection. •Ne pas utiliser pour l'injection de liquide de contraste sous forte pression. **•EVITER LE STOCKAGE A DES TEMPERATURES EXTREMES ET A L'HUMIDITE. EVITER LA LUMIERE DIRECTE DU SOLEIL. <MODE D'EMPLOI>** Pour ouvrir le blister: détacher les deux parties, en partant de la flèche. (Fig.1)

•Steril und pyrogenfrei in ungeöffneter und unbeschädigter Einzelverpackung. **<VORSICHTSMAßNAHMEN>** •Nicht verwenden, wenn die Einzelverpackung oder das Produkt beschädigt oder verschmutzt sind. •Nach Öffnen der Einzelverpackung das Produkt umgehend verwenden. •Nach einmaligem Gebrauch sicher entsorgen um Infektionsrisiken zu vermeiden. •Nicht geeignet für Druckinjektionen von Kontrastmitteln. **•VERMEIDEN SIE EXTREME TEMPERATUREN UND FEUCHTIGKEIT WÄHREND DER LAGERUNG. VOR DIREKTER SONNENBESTRAHLUNG SCHÜTZEN. <GEBRAUCHSANLEITUNG>** Öffnen der Blisterverpackung: Ziehen Sie die obere Schicht beim Pfeil beginnend ab. (Fig.1)

•Estéril y apirógeno si el envase unitario no ha sido abierto ni deteriorado. **<PRECAUCIONES>** •No utilizar si el envase unitario o el producto están manchados o dañados. •Utilizar inmediatamente después de abrir el envase unitario. •Usar una vez y destruir. El uso compartido constituye riesgo de infección. •No utilizar para inyectar medio de contraste a altas presiones. **•NO ALMACENAR A TEMPERATURAS EXTREMAS NI EN LUGARES HUMEDOS. EVITAR LA LUZ SOLAR DIRECTA. <INSTRUCCIONES DE USO>** Para abrir el envase blister: tirar de las lengüetas hacia fuera siguiendo la indicación de la flecha. (Fig.1)

•Sterile e apirogeno se in confezione individuale integra e sigillata. **<PRECAUZIONI>** •Non utilizzare se la confezione individuale o il prodotto sono danneggiati o sporchi. •Utilizzare immediatamente dopo l'apertura della confezione individuale. •Dopo averlo usato una sola volta, disfarsi del prodotto in adeguate condizioni di sicurezza per evitare rischi di infezione. •Non utilizzare per iniettare a pressione elevata mezzi di contrasto. **•NON CONSERVARE A TEMPERATURE ECCESSIVE O IN LUOGHI UMIDI. EVITARE L'ESPOSIZIONE ALLA LUCE SOLARE DIRETTA. <ISTRUZIONI PER L'USO>** Per aprire il confezionamento blister: separare i due lembi agendo sull'estremità indicata dalla freccia. (Fig.1)

•Steriel en pyrogeenvrij in een ongeopende en onbeschadigde eenheidsverpakking. **<VOORZORGSMAATREGELEN>** •Niet gebruiken wanneer de eenheidsverpakking of het product beschadigd of bevuild zijn. •Gebruik het product onmiddellijk na opening van de eenheidsverpakking. •Na eenmalig gebruik veilig vernietigen om infecties te vermijden. •Niet gebruiken voor het injecteren van contrastmedia onder hoge druk. **•VERMIJD EXTREME TEMPERATUREN EN VOCHTIGHEID TIJDENS HET BEWAREN. VERMIJD DIRECT ZONLICHT. <GEBRUIKSAANWIJZING>** Om de blisterverpakking te openen: trek aan de bovenlaag te beginnen vanaf de pijl. (Fig.1)

•Steril och pyrogenfri i en oöppnad och oskadad styckförpackning. **<FÖRSIKTIGHETSÅTGÄRDER>** •Får ej användas om styckförpackning eller produkt har skadats eller blivit nedsmutsad. •Produkten används omedelbart efter det att styckförpackningen har öppnats. •Efter engångsanvändning, kassera på ett säkert och ändamålsenligt sätt för att undvika infektionsrisk. •Får ej användas för högtrycks injektion av kontrastmedia. **•FÖRVARAS EJ VID EXTREM TEMPERATUR ELLER LUFTFUKTIGHET. UNDVIK DIREKT SOLLJUS. <BRUKSANVISNING>** För att öppna blisterförpackningen: dra isär den övre delen av förpackningen med start från pilen. (Fig.1)

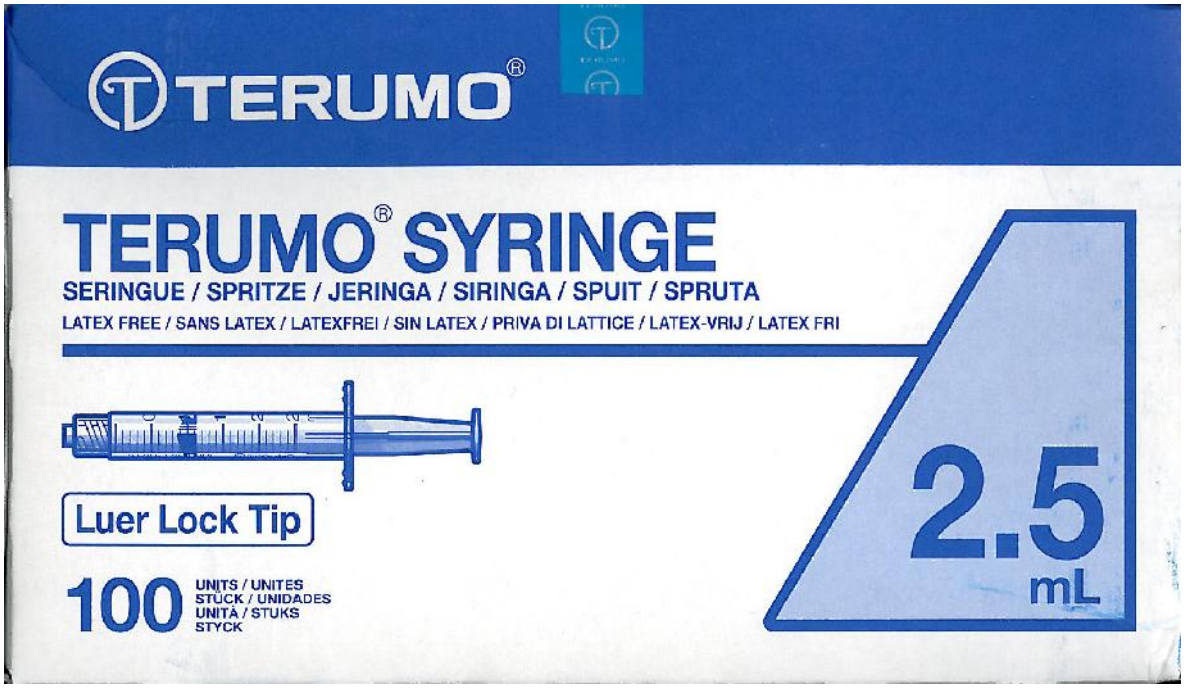
Fig.1

TERUMO CORPORATION TOKYO 151-0072, JAPAN MADE IN JAPAN

EC REP TERUMO EUROPE N.V., Interleuvenlaan 40, 3001 LEUVEN, BELGIUM

ANNEXE 2

Boite



ANNEXE 3

Etiquetage blister

N° Lot et date de péremption sur le film du blister

ANNEXE 4

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60077473 0001

Report No.: 12018187 001

Manufacturer:
Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU,TOKYO 151-0072
JAPAN

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60026344 0001

Expiry Date: 2017-08-29

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2013-05-31

Date: 2013-05-31

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Dr. H. Lüdemann

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.

TÜVRheinland®

Doc. 1/2, Rev .0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60077473 0001
Report No.: 12018187 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU,TOKYO 151-0072
JAPAN

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter

- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Spinal Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2013-05-31

Dr. H. Lüdemann

TÜVRheinland®

Doc. 2/2, Rev .0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60077473 0001
Report No.: 12018187 001

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU,TOKYO 151-0072
JAPAN

Products included:
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer
- Clinical Electronic Blood-Pressure Monitor
- Endoscopic Electromechanical Surgical Systems

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2013-05-31

Dr. H. Lüdemann

ANNEXE 5

TÜVRheinland®

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

Notified Body

Dipl.-Ing. S. Pane

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.

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Doc. 1/2, Rev. 0

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

Notified Body

Date: 2016-02-12

Dipl.-Ing. S. Pane

TÜVRheinland®

Doc. 2/2, Rev. 0

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

Notified Body

Date: 2016-02-12

Dipl.-Ing. S. Pane

ANNEXE 6

TERUMO

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.

PQB-SS003 rev. 26

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, 02/17/16
Place, date of issuance

Alvin Robles
Management Representative

PQB-SS003 rev. 26

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
1	Syringe with Needle	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	26G x ½"	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 ½"	SS+02S21381	140916Y
		22G x 1 ½"	SS+02S22381	140915Y
		23G x 1"	SS+02S23251	140708Y
3	Syringe with Needle – Lock Tip	20G x 1"	SS+03L2025M	100205F
		20G x 1 1/4"	SS+03L2032M	130511F
		20G x 1 1/2"	SS+03L2038M	130612F
		21G x 1"	SS+03L2125	121017F
			SS+03L2125M	131203F
		21G x 1 1/4"	SS+03L2132M	131226F
		21G x 1 ½"	SS+03L2138	131203F
			SS+03L2138M	131203F
			SS+03L21386	141117F
		22G x 1"	SS+03L2225M	130710F
		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 5/8"	SS+03L2516	140206F

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Declaration of Conformity
Terumo Syringe
List of Product Codes

Volume mL	Product Description	Needle Size Gauge x Length	Product Codes	Lot Number
			SS+03L2516M	130803F
3	Syringe with Needle – Luer Tip	21G x 1 ½"	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
		25G x 5/8"	SS+03S2516	131116A
5	Syringe with Needle – Lock Tip	20G x 1"	SS+05L2025M	091223C
		20G x 1 1/4"	SS+05L2032M	130801C
		21G x 1"	SS+05L2125	130923C
			SS+05L2125M	131018C
		21G x 1 1/4"	SS+05L2132M	140211R
		21G x 1 ½"	SS+05L2138	131016C
			SS+05L2138M	130615C
			SS+05L21386	141229C
		22G x 1"	SS+05L2225M	131120C
		22G x 1 1/4"	SS+05L2232	131130C
			SS+05L2232M	140210R
		22G x 1 ½"	SS+05L2238	140207C
			SS+05L2238M	130911C
		23G x 1"	SS+05L2325	140130C
		23G x 1 1/4"	SS+05L2332	140206C
	Syringe with Needle – Luer Tip	21G x 1 1/2"	SS+05S2138	130726C
			SS+05S2138M	131216C
			SS+05S21381	140214C
		22G x 1 1/4"	SS+05S2232	110529C
		22G x 1 1/2"	SS+05S2238	130810C
			SS+05S22381	140216C
		23G x 1"	SS+05S2325	130811C
		23G x 1 1/4"	SS+05S2332	131113C
			SS+05S23321	140221C
10	Syringe with Needle – Lock Tip	20G x 1"	SS+10L2025	140213L
		20G x 1 1/4"	SS+10L2032M	130922L

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Declaration of Conformity
Terumo Syringe
List of Product Codes

Volume mL	Product Description	Needle Size Gauge x Length	Product Codes	Lot Number
		20G x 1 1/2"	SS+10L2038	061206E
		21G x 1"	SS+10L2125	131108E
10	Syringe with Needle – Lock Tip	21G x 1 1/4"	SS+10L2132M	140214L
		21G x 1 1/2"	SS+10L2138	140123N
			SS+10L2138M	131204L
		22G x 1 1/4"	SS+10L2232M	140213L
		22G x 1 1/2"	SS+10L2238	131203L
			SS+10L2238M	131204L
		23G x 1"	SS+10L2325	140211L
	Syringe with Needle – Luer Tip	20G x 1 ½"	SS+10S20381	130607E
		21G x 1"	SS+10S2125	080104E
		21G x 1 ½"	SS+10S2138	140210E
			SS+10S2138M	130702E
			SS+10S21381	130720E
		22G x 1 1/4"	SS+10S2232	121013E
		22G x 1 ½"	SS+10S2238	131215E
			SS+10S22381	130805E
		23G x 1"	SS+10S2325	140119E

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Declaration of Conformity
Terumo Syringe
List of Product Codes

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
	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
20	Syringe without Needle – Lock Tip	SS+20L	131227B
		SS+20L1	140206B
		SS+20LM	140209B
	Syringe without Needle – Luer Tip	SS+20S	130513B
	Syringe without Needle – Eccentric Luer Tip	SS+20ES	140206B
		SS+20ES6	131130B
		SS+20ESM	140204B
		SS+20ES1	140203B

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Declaration of Conformity
Terumo Syringe
List of Product Codes

Volume mL	Product Description	Product Codes	Lot Number
30	Syringe without Needle – Lock Tip	SS+30L1	131105G
		SS-30L	150918G
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

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ANNEXE 7

No.DOC-PQB-TF-SS

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DECLARATION OF CONFORMITY

We, TERUMO CORPORATION
44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan

being the manufacturer of:

TERUMO Syringe

Product : Hypodermic Syringe

declare that the above products of **Class IIa** are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60077473 0001), Tillystraße 2, 90431 Nürnberg Germany, as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, July 4, 2013
(place and date of issue)

H. Nakagomi
Hiroshi Nakagomi
General Manager
Quality Assurance Department
TERUMO CORPORATION

TERUMO

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Appendix A - List of Code Number Structure

S S □ □ □ □ □ □ or
1 2 3 4 5 7

S S □ □ □ □ □ or
1 2 3 4 5

S S □ □ □ □ □ ○ ○ ○ ○ △
1 2 3 4 5 6 7

1. Product series (product type) (one digit)
   SS : Syringe
2. Destination (Japan and overseas) (two digits)
   − : Japan ＊ : Overseas
3. Nominal capacity (product type) (two digits)
   02 : 2.5mL
   05 : 5mL
   10 : 10mL
   20 : 20mL
   30 : 30mL
   50 : 50mL
4. Cylinder head shape (one or two digits)
   S : Luer Slip tip
   L : Luer Lock tip
   ES : Eccentric Luer Slip tip
   C : Catheter tip
5. Others
   Z : Gamma sterilization
   E : Electron beam sterilization
6. Injection needle type (four digits)
   Upper two digits : Needle gauge
   Lower two digits : Needle length
7. Last digit
   1 : CE display

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