Dossier d'information Euro Pharmat

DISPOSITIF MEDICAL

SERINGUES Trois pièces avec aiguille montée

1. Renseignements administratifs concernant l'entreprise		***Date de mise à jour : Septembre 2016***
1.1	**Nom : TERUMO France**	
1.2	**Adresse complète :** Bâtiment 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 23** **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 avec aiguille montée**	
2.3	**Code nomenclature : Code GMDN : 18070** **Code CLADIMED : K54BB02**	
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 révisée 2007/47/CE Selon Annexe n° 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. Elles sont constituées : ➢ d'un corps transparent doté d'un embout luer centré ou excentré et d'un bourrelet d'arrêt. Graduation conforme à la norme, impression noire. ➢ 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. ➢ L'intérieur du corps de la seringue et le joint sont siliconés. 	

2.7 **Références Catalogue** :

Tableau des références

Références	Description	Stérilisation du dispositif	Capacité graduation	Incrément	Nbre Unit/boîte	Nbre unit/carton
8SS01T25161	Tuberculine 1ml Aiguille 0,50X16mm	Rayon β	1ml	0,01	100	1800
8SS01T26131	Tuberculine 1ml Aiguille 0,45X12mm	Rayon β	1ml	0,01	100	1800
2SS02S2116	2,5ml luer centré Aiguille 0,80X16mm	OE	2,5ml	0,1	100	600
2SS02S2125	2,5ml luer centré Aiguille 0,80X25mm	OE	2,5ml	0,1	100	600
2SS02S2138	2,5ml luer centré Aiguille 0,80X40mm	OE	2,5ml	0,1	100	600
2SS02S2238	2,5ml luer centré Aiguille 0,80X40mm	OE	2,5ml	0,1	100	600
2SS02S2325	2,5ml luer centré Aiguille 0,60X25mm	OE	2,5ml	0,1	100	600
2SS02S2332	2,5ml luer centré Aiguille 0,60X32mm	OE	2,5ml	0,1	100	600
2SS02S2516	2,5ml luer centré Aiguille 0,50X16mm	OE	2,5ml	0,1	100	600
8SS05S21381	5ml luer centré Aiguille 0,80X40mm	Rayon β	6ml	0,2	100	1200
8SS05S22381	5ml luer centré Aiguille 0,70X40mm	Rayon β	6ml	0,2	100	1200
8SS05S23321	5ml luer centré Aiguille 0,60X30mm	Rayon β	6ml	0,2	100	1200
8SS10S20381	10ml luer centré Aiguille 0,90X40mm	OE	12ml	0,2	100	800
8SS10S21381	10ml luer centré Aiguille 0,80X40mm	OE	12ml	0,2	100	800
8SS10S22381	10ml luer centré Aiguille 0,70X40mm	OE	12ml	0,2	100	800

Références	Stérilisation du dispositif	Sol. Insuline ml/Unités	Longueur de l'aiguille	Nbre Unit/boîte	Nbre unit/carton
8SS01H25161	Rayon β	1ml/100U	Aiguille 0,50X16mm	100	1800
8SS01H26131	Rayon β	1ml/100U	Aiguille 0,45X12mm	100	1800

Etiquetage : Voir ANNEXES

Conditionnement/Emballages :
UCD (Unité de commande): 1 boite de 100 unités
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 :

Belgique et Philippines

POSITIONS	REFERENCES	EXPLICATIONS
1	**2 ou 8**	Lieu de fabrication 2=Belgique 8= Philippines
2-3	**BS/SS**	Seringue
4-5	**01, 02, 05, 10**	Volume en ml : **01**=1ml **02**=2ml **05**=5ml **10**=10ml
6	**T, H, S**	**T**= Tuberculine **H**= Insuline **S**= Embout centré
7-8	**20,21, 22, 23, 25, 26**	Gauge
9-10	**13, 16, 25, 32, 38**	Longueur de l'aiguille en mm
11	**1**	Affichage CE

Japon

POSITIONS	REFERENCES	EXPLICATIONS
1	**1**	Lieu de fabrication Japon
2-3	**SS**	Seringue
4-5	**05**	Volume en ml : **05**=5ml
6	**S**	**S**= Embout centré
7	**E**	**E**= stérilisation électrons Bean
8-9	**21, 22,23**	Gauge
10-11	**32, 38**	Longueur de l'aiguille en mm
12	**1**	Affichage CE

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

Eléments	Matériaux
Seringue	
Corps	Polypropylène
Piston	Polypropylène
Joint	Elastomère thermoplastique
Lubrifiant	Huile de silicone
Aiguille	
Embase	Polypropylène
Canule	Acier inoxydable
Colle	Colle époxy
Lubrifiant	Silicone

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**

Toutes mentions jugées utiles pour les précautions d'utilisation :

- **Vérifier l'intégrité du blister avant utilisation**
- **Strict usage unique**
- **Eliminer de façon sécuritaire afin d'éviter le risque de contamination**

2.9 **Domaine - Indications :**

Domaine d'utilisation (selon liste Europharmat) : **Injection**

Indications (selon liste Europharmat): **Injection ou prélèvement**

3. Procédé de stérilisation	
	DM stérile : **OUI** **Mode de stérilisation du dispositif** : **Stérilisation à l'Oxyde d'éthylène (OE) : Validation du process selon la norme EN ISO 11135-1:2007** **Stérilisation par rayonnement β (Rayon β) : Validation du process 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** :
5.2	**Sécurité biologique (s'il y a lieu)** : **Non applicable**
6. Conseils d'utilisation	
6.1	**Mode d'emploi** :
6.2	**Indications** :
6.3	**Précautions d'emploi** : **Voir mentions jugées utiles ci-dessus**
6.4	**Contre- Indications** :
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)	
	✓ **Boîte (Annexe 1)** ✓ **Certificat de marquage CE Belgique (Annexe 2)** ✓ **Déclaration de conformité Belgique (Annexe 3)** ✓ **Certificat de marquage CE Japon (Annexe 4)** ✓ **Déclaration de conformité Japon (Annexe 5)** ✓ **Certificat de marquage CE Philippines (Annexe 6)** ✓ **Déclaration de conformité Philippines (Annexe 7)** ✓ **Certificat d'absence de Latex (Annexe 8)**
9. Images (s'il y a lieu)	
	Format gif, jpeg, png

ANNEXE 1

Blister

UNIT PACKAGE 2 ml Syringe with needle 21G x 5/8"

TERUMO

SYRINGE WITH NEEDLE 2 ml

21G x 5/8"
0.8 x 16 mm

SERINGUE AVEC AIGUILLE
SPRITZE MIT KANÜLE
JERINGA CON AGUJA
SERINGA COM AGULHA
SIRINGA CON AGO
SPUIT MET NAALD
INJEKTIONSSPRUTA MED KANYL
SPRØJTE MED KANYLE
SPRØYTE MED NÅL
RUISKU NEULAN KANSSA
ΣΥΡΙΓΓΑ ΜΕ ΒΕΛΟΝΑ
ШПРИЦ С ИГЛОЙ
STRZYKAWKA Z IGŁA
FECSKENDŐ TŰVEL
STŘÍKAČKA S JEHLOU
STRIEKAČKA S IHLOU

CE 0197
STERILE EO

TERUMO EUROPE N.V.
3001 LEUVEN, BELGIUM

TERUMO

SYRINGE WITH NEEDLE 2 ml

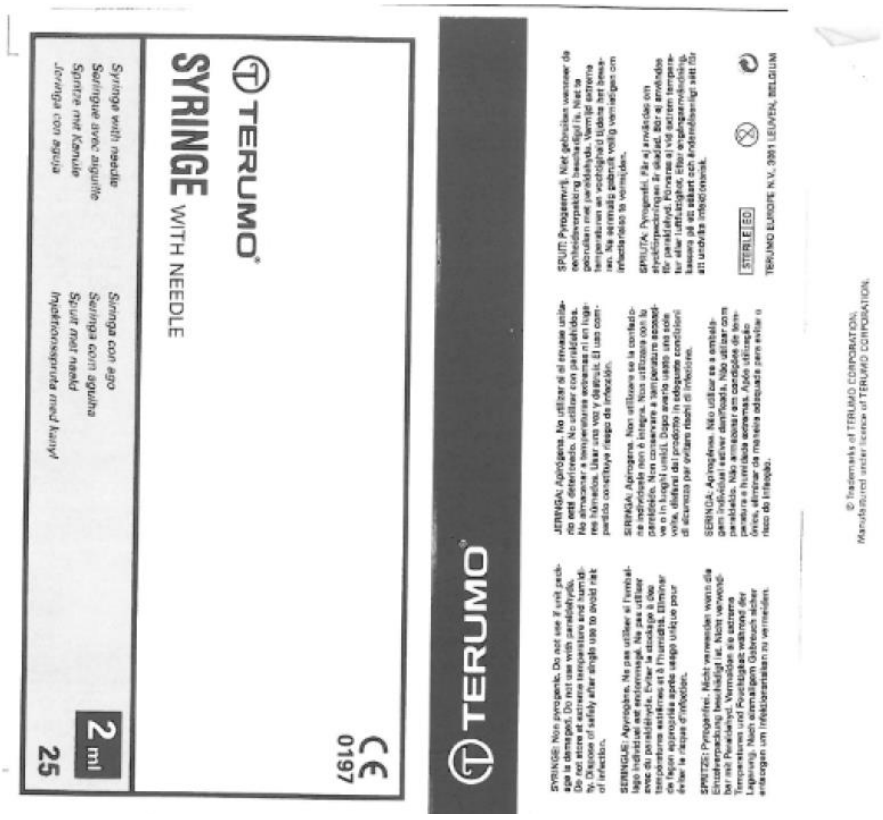
21G x 5/8"
0.8 x 16 mm

SERINGUE AVEC AIGUILLE
SPRITZE MIT KANÜLE
JERINGA CON AGUJA
SERINGA COM AGULHA
SIRINGA CON AGO
SPUIT MET NAALD
INJEKTIONSSPRUTA MED KANYL
SPRØJTE MED KANYLE
SPRØYTE MED NÅL
RUISKU NEULAN KANSSA
ΣΥΡΙΓΓΑ ΜΕ ΒΕΛΟΝΑ
ШПРИЦ С ИГЛОЙ
STRZYKAWKA Z IGŁA
FECSKENDŐ TŰVEL
STŘÍKAČKA S JEHLOU
STRIEKAČKA S IHLOU

CE 0197
STERILE EO

TERUMO EUROPE N.V.
3001 LEUVEN, BELGIUM

Boite



ANNEXE 2

TÜVRheinland®

EC Certificate

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

Registration No.: HD 60106290 0001

Report No.: 21240046 001

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products: (see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60035711 0001

Expiry Date: 2020-12-07

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: 2015-12-08

Date: 2015-12-08

Notified Body

Dipl.-Ing. D. Meier

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 60106290 0001
Report No.: 21240046 001

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Products:

- Syringes
- Needles
- Administration sets
- Blood collecting systems
- Angiographic-interventional catheter systems
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Ancillary devices for extracorporeal circuits for open heart surgery
- Mixing needles
- Blood collecting systems

Notified Body

Date: 2015-12-08

Dipl.-Ing. D. Meier

TÜVRheinland

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

Attachment to Certificate
Registration No.: HD 60106290 0001
Report No.: 21240046 001

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Additional sites included:

TERUMO EUROPE N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium

Scope: Warehouse operations and distribution of medical devices

TERUMO UK
3 Unity Grove
Knowsley Business Park South, Knowsley,
Merseyside L34 9GT, United Kingdom

Scope: Design and development, manufacture of extracorporeal circuits for open heart surgery and ancillary circuits

Notified Body

Date: 2015-12-08

Dipl.-Ing. D. Meier

ANNEXE 3

TERUMO

Rev. 30
PS-3009

DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
Interleuvenlaan 40,
3001 Leuven, Belgium

being the manufacturer of:

TERUMO® SYRINGE WITH NEEDLE

Product: **Hypodermic Syringes for manual use**
(See Appendix A for related product codes)

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 System" set out in Annex II, and by certification of Annex II.3, under the supervision of TÜV Rheinland LGA Products GmbH (Registration No: HD 60106290 0001), as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Leuven, 15 July 2016
(place and date of issue)

M.J. AERTS
EMEA Regulatory & Quality
Division Manager
TERUMO EUROPE N.V.

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TERUMO

Rev. 30
PS-3009

Appendix A – Related product codes

The product code is composed of 12 digits maximum and explained as follows:

Product code syringes with needle:

1	2	3	4	5	6	7	8	9	10	11	12
S	S	Blister Syringes new design									
Production site		-	Terumo Europe N.V.								
Product item			0	2	2.5 ml						
Item type					S	Center Luer Slip Tip					
Cannula size						2	0	20 G (0.9 mm)			
						2	1	21 G (0.8 mm)			
						2	2	22 G (0.7 mm)			
						2	3	23 G (0.6 mm)			
						2	5	25 G (0.5 mm)			
						2	6	26 G (0.45 mm)			
Needle length								1	3	12 mm = 1/2"	
								1	6	16 mm = 5/8"	
								2	5	25 mm = 1"	
								3	2	30 mm = 1-1/4"	
								3	8	40 mm = 1-1/2"	
Alphanumerical digits to distinguish from standard items											

Product code syringes provided with more than one needle:

1	2	3	4	5	6	7	8	9	10	11	12
S	S	Blister Syringes new design									
Production site		-	Terumo Europe N.V.								
Product item			2	S	2.5 ml + Surguard2 Needles						
Item type					S	Center Luer Slip Tip					
Cannula size (1)						1	8	18 G (1.2 mm)			
Cannula size (2)								2	1	21 G (= 0.8 mm)	
								2	3	23 G (= 0.6 mm)	
Cannula size (3)								23 G (= 0.6 mm)		2	3
Alphanumerical digits to distinguish from standard items											

2/2

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

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 Zertifizierungsstelle TÜVRheinland®

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

No.DOC-PQB-TF-SS

Rev.08

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

Page 1 of 2

No.DOC-PQB-TF-SS

Rev.08

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

TERUMO®

Page 2 of 2

ANNEXE 6

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.

TÜVRheinland

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 7

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.

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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

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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

ANNEXE 8

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

TPC 14_A001

September 30, 2014

DECLARATION

We, Terumo (Philippines) Corporation, hereby declare that the following products and their packaging have no components made of natural rubber latex:

- Terumo SurGuard®2 Safety Hypodermic Needle
- Terumo SurGuard®2 Hypodermic Syringe with Safety Needle
- Terumo SurGuard®3 Safety Hypodermic Needle
- Terumo SurGuard®3 Hypodermic Syringe with Safety Needle
- Terumo Syringe with or without Needle
- Terumo Insulin Syringe with or without Needle
- Terumo Syringe for oral/enteral use
- Terumo Urogard Plus Closed Urinary Drainage Bag
- Terumo Surflo Intravenous Catheter

9/30/14

Alvin Robles
Senior Manager
QA Department