Dossier d'information Euro Pharmat

DISPOSITIF MEDICAL

SERINGUES TROIS PIECES LUER LOCK

1. Renseignements administratifs concernant l'entreprise		***Date de mise à jour : Novembre 2012***
1.1	**Nom :** TERUMO France	
1.2	**Adresse complète :** Bât.Uranus Rue Hélène Boucher, 1 Parc Ariane 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 :** Sébastien RENARD	**Tel :** 01 30 96 13 03 **Fax :** 01 30 43 60 85 **e-mail :** sebastien.renard@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 **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. Insertion photos : relié au point 9  	

2.7 **Références Catalogue** :

Tableau des références

Références	Volume nominal	Capacité graduation	Incrément	Description	Nbre Unit/boîte	Nbre unit/carton
1SS02LE1	2,5ml	2,5ml	0,1	Embout centré	100	2400
8SS03L1	3ml	3ml	0,1	Embout centré	100	1800
1SS05LE1	5ml	6ml	0,2	Embout centré	100	1600
1SS10LE1	10ml	12ml	0,2	Embout centré	100	800
8SS20L1	20ml	20ml	1,0	Embout centré	50	600
1SS30LE1	30ml	35ml	1,0	Embout centré	50	400
2BS50LG*	50ml	60ml	1,0	Embout centré	25	100
2BS50LB*	50ml	60ml	1,0	Seringue opaque embout centré	25	100

* **2BS50LG** : Seringue pour pousse seringue
* **2BS50LB** : Seringue pour pousse seringue/Médicaments photosensible

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 :**

Dispositifs	Eléments	Matériaux
Seringue	Corps	Polypropylène transparent
	Piston	Polypropylène
	Joint	Elastomère thermoplastique, complexe synthétique, Polymérique, composé de Polyéthylène/Polypropylène/ Styrène (**sans latex**)

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

2.9 **Domaine - Indications :**

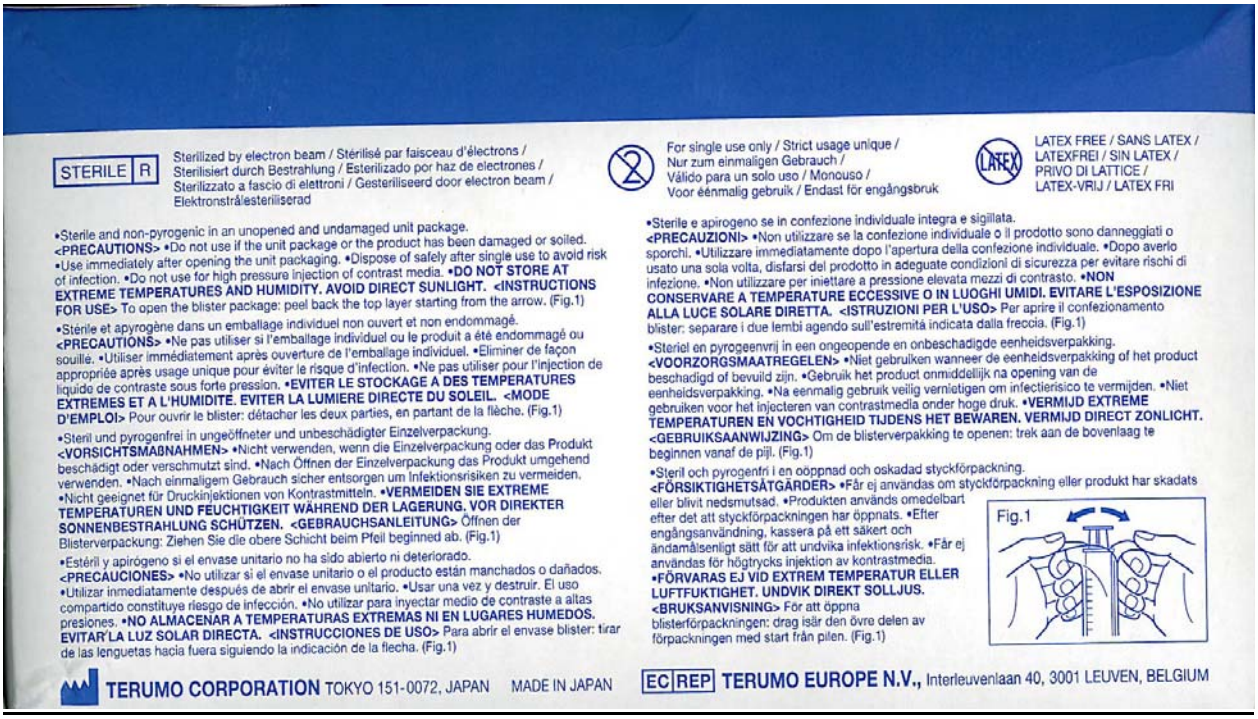
Domaine d'utilisation (selon liste Europharmat) : **Injection**
Indications (selon liste Europharmat): **Injection manuelle ou pousse seringue selon références**

3. Procédé de stérilisation :	
	DM stérile: OUI NON **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 Belgique + déclaration de conformité (Annexe 4 et 4-1)** ✓ **Certificat de marquage CE Philippines + déclaration de conformité (Annexe5 et 5-1)** ✓ **Certificat de marquage CE Japon + déclaration de conformité (Annexe 6 et 6-1)**
9. Images (s'il y a lieu)	
	Format gif, jpeg, png

ANNEXE 1

Précautions d'emploi boite



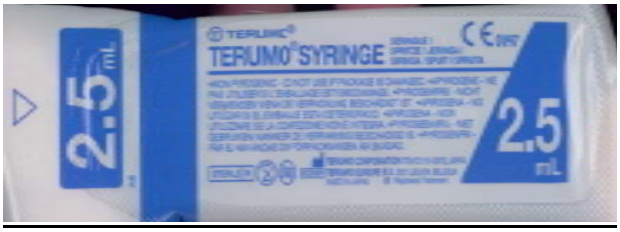
ANNEXE 2

Boite



ANNEXE 3

Etiquetage blister



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

ANNEXE 4

TÜVRheinland®

APPROVAL

EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60035711 0001

Report No.: 21150638 001

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

Scope: Design/Development and Manufacturing of Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60024159 0001

Date of Expiry: 07.12.2015

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date 08.12.2010

Dipl.-Ing. D. Meier

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜVRheinland®

Doc. 1/3, Rev. 2

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60035711 0001
Report No.: 21150638 023

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

Products:

- Syringes
- Needles
- Administration sets
- Blood collecting systems
- Accessories for short peripheral catheters
- 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
- Blood collecting systems
- Mixing needles

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2012-11-07

Dipl.-Ing. D. Meier

TÜVRheinland®

Doc. 2/3, Rev. 2

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60035711 0001
Report No.: 21150638 023

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

For the following medical devices the scope covers only the aspects of manufacture concerned with the conformity of the products with the metrological requirements:

- Blood collection weighing and mixing device

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

- Syringes for oral/enteral use

Notified Body
TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2012-11-07

Dipl.-Ing. D. Meier

TÜVRheinland®

Doc. 3/3, Rev. 2

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60035711 0001
Report No.: 21150638 023

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

Sites included:

TERUMO EUROPE N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium
Scope: Warehouse operations of medical devices

TERUMO UK
3 Unity Grove, off School Lane,
Knowsley Industrial Park South, Knowsley,
Merseyside L34 9GT, United Kingdom
Scope: Design/development and manufacture of extracorporeal circuits for open heart surgery and ancillary circuits

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2012-11-07

Dipl.-Ing. D. Meier

ANNEXE 4-1

TERUMO

Rev. 11
PS-3009

DECLARATION OF CONFORMITY

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

being the manufacturer of:

TERUMO® 50 ML SYRINGE WITHOUT NEEDLE
(with luer lock tip)

Product: **Hypodermic Syringe for use with Syringe Pump**
(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 60035711 0001), as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Leuven, 15 November 2012
(place and date of issue)

M.J. Aerts
Manager Regulatory Affairs
TERUMO EUROPE N.V.

1/2

TERUMO

Rev. 11
PS-3009

Appendix A – Related product codes

The product code is composed of 7 digits and explained as follows:

Product code 50 ml syringe:

1	2	3	4	5	6	7
B	S	Blister Syringes				
Production site		-	Terumo Europe N.V.			
Product item			5	0	50 ml	
Item type					L	G
			Luer Lock Tip – opaque syringe		L	B

ANNEXE 5

TÜVRheinland®

APPROVAL

EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60038153 0001

Report No.: 60013826 003

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

Scope: Manufacture of Disposable Sterile Medical Devices

(See attachment for products included)

Replaces Approval, Registration No.: DD 60029244 0001

Date of Expiry: 11.02.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

TÜV Rheinland LGA Products GmbH – TÜVRheinland – Zertifizierungsstelle

Date 08.03.2011

Dipl.-Ing. O. Masur

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: DD 60038153 0001
Report No.: 60013826 003

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

Scope:
Aspects of manufacture concerned with securing and maintaining sterile conditions

- Syringes without Needles
- Urinary Drainage Bags
- Syringes for Oral/Enteral

Sterilization Method:
Irradiation using Electron Beam

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Certification Body

Date 08.03.2011

Dipl.-Ing. O. Masur

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: DD 60038153 0001
Report No.: 60013826 003

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

Scope:

Products included:

- Syringes with Needles
- Intravenous Catheter
- Safety Needles
- Syringes with Safety Needles

Sterilization Method:
Irradiation using Electron Beam

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Certification Body

Date 08.03.2011

Dipl.-Ing. O. Masur

TÜV, TÜEV and TÜV are registered trademarks. Utilisation and application requires prior approval.

ANNEXE 5-1

TERUMO

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

DECLARATION OF CONFORMITY

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

We declare under our sole responsibility that the

Medical Device	Terumo Syringe without Needle			
Product Code	SS+01T	SS+05L1	SS+10S	SS+20SM
	SS+01TM	SS+05L6	SS+10S6	SS+20ES
	SS+01T6	SS+05LM	SS+10ES	SS+20ES6
	SS+03L	SS+05S	SS+10ESM	SS+20ES1
	SS+03L1	SS+05S6	SS+20L	SS+20ESM
	SS+03LM	SS+10L	SS+20L1	SS+30L1
	SS+03L6	SS+10L1	SS+20LN	SS+60C
	SS+03S	SS+10L6	SS+20LM	SS+60CM
	SS+03S6	SS+10LM	SS+20S	SS+01NA
	SS+05L	SS+01T1	SS+01H1	

Of Class	Class IIa, Rule 2 Annex IX of MDD

meets all the provisions of the Directive 93/42/EEC as amended which apply to it.

Applied harmonized standards, national standards or other normative documents	EN 556-1:2001	ISO 10993-11:2006
	EN ISO 14971:2009	ISO 7886-2:1996
	EN 980:2008	ISO 7886-1:1993 Cor1:1995
	EN 1041:2008	EN ISO 11137-1:2006
	EN ISO 11607-1:2009	EN ISO 11137-2:2007
	EN ISO 11607-2:2006	ISO 11137-3:2006
	ISO 14644-1:1999	ISO 594-1:1986
	ISO 14644-2:2000	ISO 594-2:1998
	EN ISO 10993-1:2009	ISO 11737-1:2006
	ISO 10993-4:2002 Amd 1:2006	ISO 11737-2:2009
	ISO 10993-5:2009	ISO 8537:2007
	ISO 10993-10:2010	

Conformity Assessment Procedure	MDD 93/42/EEC as amended, Annex VII combined with the provisions set out in Annex V "Production Quality Assurance"

Terumo Syringe
PQB-SS003 rev.16

Notified Body	TUV Rheinland LGA Products GmbH (Registration No. DD 60038153 0001), authorized by the German Competent Authority and carrying the Notified Body No. 0197
Address	Tillystrasse 2, 90431 Nurnberg, Germany

Philippines, 9/8/11
Place, Date of Issuance

Bernie Salvador
Manager/Quality Assurance

Terumo Syringe
PQB-SS003

rev.16

ANNEXE 6

TÜVRheinland®

APPROVAL

EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60026344 0001

Report No.: 12018114 001

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

Scope: Design/Development and Manufacture of Medical Devices

(see attachement for products included)

Replaces Approval, Registration No.: HD 60012340 0001

Date of Expiry: 12.08.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

TÜV Rheinland Product Safety GmbH Zertifizierungsstelle

Cologne, 07.09.2009

Dr. H. Lüdemann

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜVRheinland®

Doc. 1/2, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HD 60026344 0001
Report No.: 12018114 003

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

Scope:

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

Certification Body

TÜVRheinland LGA Products GmbH Zertifizierstelle

Date 21.04.2011

Dipl.-Ing. D. Meier

TÜVRheinland

Doc. 2/2, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HD 60026344 0001
Report No.: 12018114 003

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

Scope:

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
Epidural Anesthesia Kit
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

Certification Body

TÜVRheinland
Zertifizierungsstelle

Date 21.04.2011

Dipl.-Ing. D. Meier

ANNEXE 6-1

No.DOC-PQB-TF-SS

Rev.06

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 Annex I and Annex II 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, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60026344 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
This Declaration of Conformity is only valid in conjunction with each product release documents.

Tokyo, November 9, 2011
(place and date of issue)

Hiroshi Nakagomi
General Manager
Quality Assurance Department
TERUMO CORPORATION

TERUMO

Page 1 of 2

No.DOC-PQB-TF-SS

Rev.06

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 : Slip tip
   L : Round lock
   ES : Cross 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