CS-DEC-107 Ver1

TERUMO

TERUMO CLINICAL SUPPLY CO., LTD.

DECLARATION OF CONFORMITY

Medical devices

We hereby declare that the distributed CE marked products, specified below, conform to the type(s) covered by the EC Design-Examination Certificate, reference number: 2125694DE01, issued on October 28, 2009 and delivered by KEMA Quality B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices as last amended by 2007/47/EC.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class III, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive, and is described in the CE Marking of Conformity Certificate, reference number: 2125694CE01, issued on October 28, 2009 and delivered by KEMA Quality B.V..

This declaration is supported by the Quality System certification based on the harmonized standards EN ISO 13485, Quality System Certificate with reference number: 2125269 issued on May 12, 2009 and delivered by KEMA Quality.

This Declaration of Conformity covers thrombectomy catheter as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

Manufacture: TERUMO CLINICAL SUPPLY CO., LTD.
No3,Kawashima-Takehayamachi,Kakamigahara,
Gifu, 501-6024, JAPAN

EU Representative is; TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Date of issue November 18, 2009

Signature: Koji Iida Date: November 18, 2009

Koji Iida
General Manager of Quality assurance Department

Annex: Product list (CS-DEC-107-List Ver1)

TERUMO

TERUMO CLINICAL SUPPLY CO., LTD.

PRODUCT LIST

Product name: Terumo Aspiration Catheter
(Aspiration Catheter)

This product list belongs to the Declaration of Conformity identified by CS-DEC-107 Ver1 and specifies the CE marked products concerned that TERUMO CLINICAL SUPPLY CO., LTD. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as last amended by 2007/47/EC. The following list identifies the products by code number and by type name.

Code Number	Type Name	Date of CE Marking
EG1502	ELT2-6FGC-140-RX-ST	November 18, 2009
EG1552	ELT2-7FGC-140-RX-ST	November 18, 2009
EG1602	ELT3-6FGC-140-RX-ST	November 18, 2009
EG1652	ELT3-7FGC-140-RX-ST	November 18, 2009

Date of issue November 18, 2009

Signature: Koji Iida Date: November 18, 2009

Koji Iida
General Manager of Quality Assurance Department