CS-DEC-107 Ver.10

TERUMO

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 9 July 2018 and delivered by DEKRA Certification 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 under Rule 6 of Annex IX in 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 9 July 2018 and delivered by DEKRA Certification 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 5 June 2018 and delivered by DEKRA Certification B.V..

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.
3, Kawashima-Takehayamachi, Kakamigahara,
Gifu, 501-6024, Japan

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

Date of issue 9 July 2018

Signature: Koji Iida Date: 9 July 2018

Koji Iida
General Manager of Quality Assurance Department,
TERUMO CLINICAL SUPPLY Co., Ltd.

Annex: Product list (CS-DEC-107-List Ver.10)

Digitally signed by Grabazei Alexandru
Date: 2020.09.09 09:38:30 EEST
Reason: MoldSign Signature
Location: Moldova

TERUMO

PRODUCT LIST

Product name: ELIMINATE
(Aspiration Catheter)

This product list belongs to the Declaration of Conformity identified by CS-DEC-107 Ver.10 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
EG1401	ELT8FGC-140-RX	November 18, 2009
EG1402	ELT8FGC-140-MRX-ST	November 18, 2009
EG1403	ELT8FGC-125-MRX-ST	November 18, 2009
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 9 July 2018

Signature: Koji Date: 9 July 2018

Koji Iida
General Manager of Quality Assurance Department,
TERUMO CLINICAL SUPPLY Co., Ltd.