

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2125694DE01

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

TERUMO CLINICAL SUPPLY CO., LTD.

3 Kawashima-Takehayamachi

Kakamigahara

Gifu 501-6024

Japan

For the product

Thrombectomy catheters: type aspiration catheters: Extractor and Eliminate catheters

Documents, that form the basis of this certificate:

Certification Notice 2125694CN, initially dated 28 October 2009

CE Marking of Conformity 2125694CE01

Addendum, initially dated 9 July 2018

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 9 July 2023

Issued for the first time: 28 October 2009

Reissued: 9 July 2018

DEKRA Certification B.V.



drs. G.J. Zoetbrood
Managing Director



ing. A.A.M. Laan
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2125694DE01

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Thrombectomy catheters: type aspiration catheters: Extractor and Eliminate catheters

Issued to:

TERUMO CLINICAL SUPPLY CO., LTD.
3 Kawashima-Takehayamachi
Kakamigahara
Gifu 501-6024
Japan

This certificate covers the following product(s):

Type No.	ELIMINATE Code No.	Extractor Code No.
ELT8FGC-140-RX	EG1401	
ELT8FGC-140-MRX-ST	EG1402	
ELT8FGC-125-MRX-ST	EG1403	
ELT2-6FGC-140-RX-ST	EG1502	CG1502
ELT2-7FGC-140-RX-ST	EG1552	CG1552
ELT3-6FGC-140-RX-ST	EG1602	CG1602
ELT3-7FGC-140-RX-ST	EG1652	CG1652

Initial date: 9 July 2018

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