

# EC CERTIFICATE

Number: 2125694CE01

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

(Devices in Class IIa, IIb or III)

Manufacturer:

**TERUMO CLINICAL SUPPLY CO., LTD.**

**3 Kawashima-Takehayamachi**

**Kakamigahara**

**Gifu 501-6024**

**Japan**

For the product category(ies)

**Intravascular catheters**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

Documents, that form the basis of this certificate:

**Certification Notice 2125694CN, initially dated 28 October 2009**

**Addendum, initially dated 28 October 2009**

DEKRA hereby declares that the above mentioned manufacturer 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. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the 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: 2125694CE01

1/1

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Intravascular catheters

Issued to:

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

This certificate covers the following product(s):

Thrombectomy Catheters: Extractor and Eliminate

Initial date: 28 October 2009  
Revision date: 11 April 2014

DEKRA Certification B.V.

A blue ink signature of drs. G.J. Zoetbrood, written in a cursive style.

drs. G.J. Zoetbrood  
Managing Director

A blue ink signature of ing. A.A.M. Laan, written in a cursive style.

ing. A.A.M. Laan  
Certification Manager

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