

## **DECLARATION OF CONFORMITY**

**We, TERUMO CORPORATION**  
**44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan**

being the manufacturer of:

### **RADIFOCUS Torque Device**

**Product : Wire Twister**

declare that the above products of **Class I sterile** 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, 5 of the Directive, relating to the "EC Declaration of Conformity" set out in Annex VII, combined with the provisions set out in Annex V "Production Quality Assurance" and by certification of Annex V limited to the aspects of the manufacture concerned with securing and maintaining sterile conditions, under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: DD 60145254 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

Tokyo, February 10, 2020

(place and date of issue)

A blue ink signature of Toshio Nakashima.

Toshio Nakashima

General Manager

Quality Assurance Department  
TERUMO CORPORATION

## Appendix A - List of Code Number Structure

X X \* R F 0 2 M  
1 2 3 4 5 6 7 8

Character number	Characters	Meaning
1-2	Product type	XX : other (Accessory device)
3	Destination	* : for export
4-5	Product group	RF : RADIFOCUS system
6-7	Accessory device type	02 : Torque Device
8	Package indication	M : Multi-language

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60145254 0001

**Report No.:** 12031336 022

**Manufacturer:** Terumo Corporation  
44-1, 2-chome, Hatagaya  
Shibuya-Ku, Tokyo  
151-0072 Japan

**Products:** see attachement for products included

Replaces Approval, Registration No.: DD 60121892 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2019-12-23

**Date:** 2019-12-23



**Notified Body**

*M. Aihara*  
**M.Sc. M. Aihara**

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** DD 60145254 0001  
**Report No.:** 12031336 022

**Manufacturer:** Terumo Corporation  
44-1, 2-chome, Hatagaya  
Shibuya-Ku, Tokyo  
151-0072 Japan

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

- Sampling Site Coupler
- Radial Artery Hemostasis Band
- Wire Twister

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 Scale



**Notified Body**

*M. Aihara*

**Date:** 2019-12-23

**M.Sc. M. Aihara**



# Certificate

**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 1485480-1

Organization: Terumo Corporation  
44-1, 2-chome, Hatagaya  
Shibuya-ku, Tokyo  
151-0072 Japan

Scope: Design and Development, Manufacture, Distribution and Service of

- Angiographic Catheter and Accessories
- Anti-adhesion System
- Balloon Dilatation Catheter
- Blood Collection/Transfusion Device and Accessories
- Blood Glucose Monitoring system
- Cartridge Injection System
- Catheter Introducer and Accessories
- Electronic Sphygmomanometer
- Electronic Thermometer
- Embolization Prosthesis and Accessories
- Endoscopic Vessel Harvesting System
- Extracorporeal Circulation Device and Accessories
- Falloposcopic Tuboplasty Device and Accessories
- Guide Wire and Accessories
- Guiding/Micro Catheter and Accessories
- Infusion Pump
- Infusion Set and Accessories

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150241635-301  
Effective date: 2021-08-30  
Expiry date: 2023-08-29  
Issue date: 2021-08-29



Michiaki Aihara  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1485480-1

Organization: Terumo Corporation  
44-1, 2-chome, Hatagaya  
Shibuya-ku, Tokyo  
151-0072 Japan

- Intravascular Imaging Catheter and Accessories
- Intravascular Imaging System and Accessories
- Intravenous Catheter
- Left-Ventricular Assist System
- Needle
- Open-heart surgery devices and Accessories
- Oral Care Device and Accessories
- Peritoneal Dialysis Device and Accessories
- Pneumatically-powered Massager
- Prefillable Syringe
- Pulse Oximeter
- Radial Artery Hemostasis Device and Accessories
- Stent System
- Syringe
- Syringe Infusion Pump
- Syringe with Needle
- Thrombus Removal Device
- Tube Catheter and Accessories
- Urine test strip
- Vascular Closure Device
- Vascular Inspection/Treatment Kit
- Vascular prosthesis and Accessories
- Wearable Infusion Pump

Report No.: 150241635-301  
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*Michiaki Aihara*  
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TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1485480-1

Organization: Terumo Corporation  
44-1, 2-chome, Hatagaya  
Shibuya-ku, Tokyo  
151-0072 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Terumo Corporation 44-1, 2-chome, Hatagaya Shibuya-ku, Tokyo 151-0072 Japan	Aspects related to Design and Development, Manufacture, Distribution and Service.
/02	c/o Terumo Corporation - Tokyo office 3-20-2, Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Aspects related to Design and Development and activities related to corporate management processes.
/03	c/o Terumo Corporation, Shonan Center 1500, Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Aspects related to Distribution and activities related to customer communication processes.

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## RADIFOCUS® TORQUE DEVICE

Accessories



The Radifocus Torque Device is a supportive device that is intended mainly for use when guiding a disposable guidewire, which is used for percutaneous angiography and treatment under fluoroscopy, to the objective site.

### Product Characteristics

- Torque device compatible with guidewires 0.010" (0.25 mm) to 0.038" (0.97 mm)

### Item Reference

XX\*RF02M

Please quote above item reference codes when placing an order

## RADIFOCUS® HEMOSTATIC VALVE

Accessories



A hemostasis valve prevents blood reflux when a catheter is inserted in a vessel for angiographic or other purposes.

### Product Characteristics

- Cross-cut valve
- Compatible up to 7 Fr catheter
- With side tube and 3-Way Stopcock

### Item Reference

RF\*VA713M

Please quote above item reference codes when placing an order



AGENTIA MEDICAMENTULUI  
SI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip

Denumire

I.3. Certificatul CE

Certificat CE

I.2. Declaratia de conformitate CE

Declaratia de conformitate CE

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DM000191023

DISPOZITIV DE ROTIRE A GHIDULUI PENTRU CATETER

Radfocus® Torque Device

Wire Twister

XX®RF02M

Japonia

TERUMO CORPORATION

F.C.P.C. DATACONTROL S.R.L.

A07.P5-01.Rg04-370

17-12-2018

✓

Содержит(Producatorul, "Terumo") И Содержит(NameMake, "Torque Device")

Очистить

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