

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
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Shibuya-Ku, Tokyo
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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



Maihara

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

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Michihara

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

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

DECLARATION OF CONFORMITY

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

being the manufacturer of:

TR Band

Radial Artery Haemostasis Band

Product : Bandage, Pressure

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)



Toshio Nakashima

General Manager

Quality Assurance Department

TERUMO CORPORATION

Appendix A - List of Code Number Structure

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

Character number	Characters & Meaning
1, 2	Product category XX: Other (Accessory)
3	Destination *: for export
4, 5	Name of product family RF: RADIFOCUS system
6, 7	Product name 06: TR Band
8	Spare No indication after 7 digits: standard size item L: L size item

TR Band®



Radial Artery Compression Device

TR Band® is a compression device to assist patent haemostasis of the radial artery after transradial procedure. TR Band® assists in maintaining radial artery patency at the time of haemostasis, in order to prevent future radial artery occlusion (RAO).¹

Product Characteristics

- Selective compression of the radial artery to allow blood return and preserve patency¹
- Transparent structure for visual control of the puncture site
- Velcro² straps make application fast and simple
- Two band lengths available for a precise fit and optimal patient comfort¹

¹ Rathore S et al. Catheter Cardiovasc Interv 2010;76:660-667

² Velcro® is a registered trademark of Velcro Industries B.V.

General specifications

Maximum air injection volume	18 ml
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Item specifications

Size	Code
Large 29 cm	TRB29-LRG
Large 29 cm	XX*RF06L
Standard 24 cm	XX*RF06
Standard 24 cm	TRB24-REG

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. Declarația de conformitate CE	Declarația de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
DM000196904	BANDĂ DE COMPRESIE ARTERIAL-RADIALĂ	TR BAND®		XX*RF06L	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	
DM000196903	BANDĂ DE COMPRESIE ARTERIAL-RADIALĂ	TR BAND®		XX*RF06	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	

✓ [Содержит\(NameMake\)_TR_Band](#)