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 patency[1]*
- *Transparent structure for visual control of the puncture site*
- *Velcro[2] straps make application fast and simple*
- *Two band lengths available for a precise fit and optimal patient comfort[1]*

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

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

IS803/56GB1219KAIV

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.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.

TÜVRheinland®

Doc. 1/1, Rev.0

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® III Zertifizierungsstelle

Notified Body

Date: 2019-12-23

M.Sc. M. Aihara

Certificate

TÜVRheinland®

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
- Solution Administration Sets
- Needles
- Syringes
- IV Catheters
- Blood Collection Systems
- Sterile Tube Connecting Systems
- Blood Glucose Monitoring Systems
- Stents
- Catheter and Guide Wire Systems
- Oxygenator Systems
- Extension Tube
- Blood Transfusion Systems
- Apheresis Systems
- Filter Systems
- Infusion Pumps
- Syringe Infusion Pumps
- Clinical Electronic Blood-Pressure Monitors

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.: 12031336 025

Effective date: 2020-10-23

Expiry date: 2021-08-29

Issue date: 2020-10-23

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

M.Sc. M. Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

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

- Clinical Electronic Thermometer
- Medical Equipments for Blood Collection
- Medical Equipments for APD Systems
- Vascular Grafts
- Coronary Optical Coherence Tomography Systems
- Prefillable Syringes
- Portable insulin infusion pump
- Portable insulin infusion administration set

Report No.: 12031336 023

Effective date: 2020-10-23

Expiry date: 2021-08-29

Issue date: 2020-10-23

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

M.Sc. M. Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

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

No.	Facility	Scope
/02	Terumo Corporation - Tokyo office 3-20-2 Nishi-Shinjuku Shinjuku-ku, Tokyo 163-1450 Japan	Activities related to corporate management processes
/03	Terumo Corporation, Shonan Center 1500 Inokuchi, Nakai-machi Ashigarakami-gun, Kanagawa 259-0151 Japan	Activities related to customer communication processes and distribution of active, non-active and IVD medical devices

Report No.: 12031336 023

Effective date: 2020-10-23

Expiry date: 2021-08-29

Issue date: 2020-10-23

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

M.Sc. M. Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TERUMO

No.DOC-DQ010- 0760

Rev.10

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