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
- 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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Michiaki 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

- 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
Effective date: 2021-08-30
Expiry date: 2023-08-29
Issue date: 2021-08-29

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Michiaki 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

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.

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60145252 0001

Report No.: 12031336 018

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

Products: see attachement for products included

Replaces Approval, Registration No.: HD 60121893 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-12-23

Date: 2019-12-23

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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.

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 15:37:55 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Products included:

- Blood Bags
- Blood Donor Set
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2019-12-23

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60145252 0001
Report No.: 12031336 018

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

Products included:

- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Date: 2019-12-23

M.Aihara

M.Sc. M. Aihara

TERUMO

No.DOC-DQ010-0831
Rev.04

DECLARATION OF CONFORMITY

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

being the manufacturer of:

Tercross

PTA Dilatation Catheter (OTW)

Product : PTA Dilatation Catheter (OTW)

declare that the above products of **Class IIa** 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, 2 and 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II, excluding Section 4 under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60145252 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

Digitally signed by Grabazei Alexandru
Date: 2020.04.09 15:37:58 EEST
Reason: MoldSign Signature
Location: Moldova

Appendix A - List of Code Number Structure

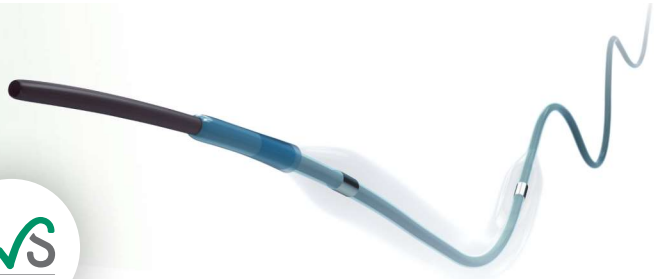
B	D	—	T	□	□	□	□	□	□	□	□
1	2	3	4	5	6	7	8	9	10	11	12

Character number	Characters	Denotation
1-2	Product name	BD: PTA CATHETER
3	Destination	-: for export/ domestic use
4	Product name	T: Tercross (OTW)
5-6	Balloon diameter	12: 1.25 mm 15: 1.5 mm 20: 2.0 mm 25: 2.5 mm 30: 3.0 mm 35: 3.5 mm 40: 4.0 mm
7-(8), 9*	Balloon length	20: 20 mm 40: 40 mm 80: 80 mm 120: 120 mm 150 : 150 mm 200: 200 mm
(9), 10*	Catheter length	P: 100 cm Q: 148 cm
(10), 11*	Adaptation wire	4: Wire adaptation of 0.014''
(11), 12*	Place of destination	E: for domestic market/ export

*:When balloon length is 2 digits, digit numbers are adapted (8)~(11)

When balloon length is 3 digits, digit numbers are adapted 9*~12*

Tercross®



Balloon Dilatation Catheter

Tercross® is a Percutaneous Transluminal Angioplasty (PTA) balloon dilatation catheter for peripheral indications.

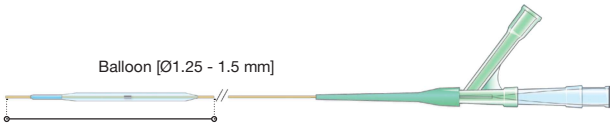
The Tercross® is designed specifically to dilatate stenosis of peripheral arteries, such as iliac, femoral, popliteal, infra-popliteal and renal artery other than cephalic, cervical and cardiac artery.

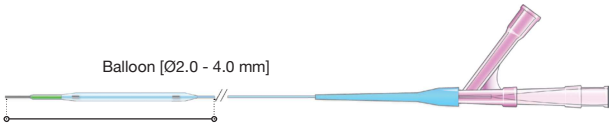
Product Characteristics

Outstanding crossability
- ***Lowest balloon crossing profile, hydrophilic coating, provides reliable crossability***
- ***Extreme support, OTW**, seamless, polymer shaft offers enhanced pushability, adequate kink resistance and fast deflation times***

Extensive pressure working range
- ***The balloon can be inflated up to a Rated Burst Pressure (RBP) of 20 atm (2026 kPa) for efficient and successful recanalization***

Wide size mix
- ***A wide choice of balloon diameters (Ø 1.25 - 4.0 mm) and lengths (20 - 200 mm) covers all clinical needs***





Specifications

Guidewire compatibility	0.014" / 0.36 mm
Usable shaft length	100 cm, 148 cm
Balloon folding	2 folded (Ø1.25 mm, 1.5 mm) / 3 folded (Ø2.0-4.0 mm)
Coating	Hydrophilic
Shaft	proximal: Ø1.25 mm, 1.5 mm: 3.2 Fr (1.07 mm) / Ø2.0-4.0 mm: 3.6 Fr (1.21 mm) distal: Ø1.25 mm, 1.5 mm: 2.5 Fr (0.83 mm) / Ø2.0-4.0 mm: 3.0 Fr (1.00 mm)

Shaft length: 100 cm

	Balloon length / Product code					
Balloon diameter	**20 mm**	**40 mm**	**80 mm**	**120 mm**	**150 mm**	**200 mm**
1.25	BD-T1220P4E	-	-	-	-	-
1.50	BD-T1520P4E	-	-	-	-	-
2.00	-	BD-T2040P4E	BD-T2080P4E	BD-T20120P4E	BD-T20150P4E	BD-T20200P4E
2.50	-	BD-T2540P4E	BD-T2580P4E	BD-T25120P4E	BD-T25150P4E	BD-T25200P4E
3.00	-	BD-T3040P4E	BD-T3080P4E	BD-T30120P4E	BD-T30150P4E	BD-T30200P4E
3.50	-	BD-T3540P4E	BD-T3580P4E	BD-T35120P4E	BD-T35150P4E	BD-T35200P4E
4.00	-	BD-T4040P4E	BD-T4080P4E	BD-T40120P4E	BD-T40150P4E	BD-T40200P4E

Shaft length: 148 cm

	Balloon length / Product code					
Balloon diameter	**20 mm**	**40 mm**	**80 mm**	**120 mm**	**150 mm**	**200 mm**
1.25	BD-T1220Q4E	-	-	-	-	-
1.50	BD-T1520Q4E	-	-	-	-	-
2.00	-	BD-T2040Q4E	BD-T2080Q4E	BD-T20120Q4E	BD-T20150Q4E	BD-T20200Q4E
2.50	-	BD-T2540Q4E	BD-T2580Q4E	BD-T25120Q4E	BD-T25150Q4E	BD-T25200Q4E
3.00	-	BD-T3040Q4E	BD-T3080Q4E	BD-T30120Q4E	BD-T30150Q4E	BD-T30200Q4E
3.50	-	BD-T3540Q4E	BD-T3580Q4E	BD-T35120Q4E	BD-T35150Q4E	BD-T35200Q4E
4.00	-	BD-T4040Q4E	BD-T4080Q4E	BD-T40120Q4E	BD-T40150Q4E	BD-T40200Q4E

Please quote above item reference codes when placing an order

Not secure | 89.32.230.138:8081/dispozitive/

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declaratia de conformitate CE

DM000139745	Cateter cu balon noncompliant pentru angioplastie periferică	Tercross® - PTA Dilatation Catheter (OTW)	4.00mm x 150mm	BD-T40150P4E	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-203	27-07-2018	
DM000139755	Cateter cu balon noncompliant pentru angioplastie periferică	Tercross® - PTA Dilatation Catheter (OTW)	3.00mm x 40mm	BD-T3040Q4E	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-203	27-07-2018	
DM000139735	Cateter cu balon noncompliant pentru angioplastie periferică	Tercross® - PTA Dilatation Catheter (OTW)	4.00mm x 80mm	BD-T4080P4E	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-203	27-07-2018	
DM000139737	Cateter cu balon noncompliant pentru angioplastie periferică	Tercross® - PTA Dilatation Catheter (OTW)	2.50mm x 120mm	BD-T25120P4E	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-203	27-07-2018	
DM000139762	Cateter cu balon noncompliant pentru angioplastie periferică	Tercross® - PTA Dilatation Catheter (OTW)	3.50mm x 80mm	BD-T3580Q4E	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-203	27-07-2018	
DM000139747	Cateter cu balon noncompliant pentru angioplastie periferică	Tercross® - PTA Dilatation Catheter (OTW)	2.50mm x 200mm	BD-T25200P4E	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-203	27-07-2018	
DM000139734	Cateter cu balon noncompliant pentru angioplastie periferică	Tercross® - PTA Dilatation Catheter (OTW)	3.50mm x 80mm	BD-T3580P4E	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-203	27-07-2018	
DM000139725	Cateter cu balon noncompliant pentru angioplastie periferică	Tercross® - PTA Dilatation Catheter (OTW)	1.5mm x 20mm	BD-T1520P4E	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-203	27-07-2018	
DM000139780	Cateter cu balon noncompliant pentru angioplastie periferică	Tercross® - PTA Dilatation Catheter (OTW)	3.50mm x 200mm	BD-T35200Q4E	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-203	27-07-2018	
DM000139774	Cateter cu balon noncompliant pentru angioplastie	Tercross® - PTA Dilatation Catheter (OTW)	3.50mm x 150mm	BD-T35150Q4E	Japonia	TERUMO CORPORATION	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-203	27-07-2018	