

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following scope:

**Design and development, manufacture and distribution
of active, non-active medical devices and IVD
medical devices and servicing of active medical devices
(see attachments for products and sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-08-30
Certificate Registration No.: SX 60121908 0001
An audit was performed. Report No.: 12031336 001
This Certificate is valid until: 2019-03-30

Certification Body



Date 2017-08-18



M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60121908 0001
Report No.: 12031336 001

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

Scope:

Products included:

- 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

Certification Body



Date: 2017-08-18

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60121908 0001
Report No.: 12031336 001

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

Scope:

Products included:

- Clinical Electronic Blood-Pressure Monitors
- Clinical Electronic Thermometer
- Medical Equipments for Blood Collection
- Medical Equipments for APD Systems
- Vascular Grafts
- Coronary Optical Coherence Tomography Systems
- Prefillable Syringes

Site included:

Terumo Corporation - Tokyo Office
3-20-2, Nishi-Shinjuku, Shinjuku-ku, Tokyo, 163-1450 Japan

Scope:

Activities related to corporate management processes

Certification Body



Date: 2017-08-18

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
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Registration No.: SX 60121908 0001
Report No.: 12031336 001

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

Scope:

Sites included:

Terumo Corporation - Shonan Center
1500, Inokuchi, Nakai-machi, Ashigarakami-gun, Kanagawa,
259-0151, Japan

Scope:

Activities related to customer communication processes and
distribution of active, non-active and IVD medical devices

Terumo Corporation Blood Management Company
Transfusion Business Group - c/o Terumo BCT Japan Inc.,
Takanawa Office
3-20-14 Higashi-Gotanda, Shinagawa-ku, Tokyo,
141-0022, Japan

Scope:

Activities related to corporate management processes

Certification Body



Date: 2017-08-18

M. Aihara
M.Sc. M. Aihara

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 613749**
Issued To: **Terumo Corporation**
44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
151-0072
Japan

In respect of:

Crosswire, Crosswire NT, and Runthrough NS PTCA Guidewires

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 August 2014**

Date: **16 March 2016**

Expiry Date: **31 July 2019**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

EC Design-Examination Certificate

Supplementary Information to CE 613749

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

Crosswire

C W *

1 2 3 4 5 6 7 8 9 10 11 12

Character number	Denotation	
1-2	Product name	CW: CROSSWIRE (Cross Wire)
3	Destination	*: for export
4	Core wire material	N: Nickel-Titanium alloy (NiTi)
5	Tip configuration	S: Straight (Sheapable)
6-7	Outer diameter of Guide wire	Character: 14, Diameter: 0.014"
8-9	Guide wire length	Character: 18, length (cm): 180
10	Flexibility	H: Hard, S: Standard
11	Butting load*	Character 4 8 Load (g) 40 80
12	Languages used for labelling	M: Multi-language

*: Only for Hard type. For other types, the 11th digit indicates the languages used for labelling

First Issued: **01 August 2014**

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Supplementary Information to CE 613749

Issued To:

Terumo Corporation
44-1, 2-chome
Hatagaya
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Japan

Crosswire Product Codes:

Outer Diameter (inch)	Product Code	Specifications	
		Length (cm)	Tip Shape
0.014"	CW*NS1418SM	180	Straight
0.014" (Hard type)	CW*NS1418H4M	180	Straight
	CW*NS1418H8M	180	Straight

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Crosswire NT

C W * □ □ □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Denotation	
1-2	Product name	CW: CROSSWIRE NT (Cross Wire NT)
3	Destination	*: for export
4	Core wire material	N: Nickel-Titanium alloy (NiTi)
5	Tip configuration	A: Straight
6-7	Outer diameter of Guide wire	Character: 14, Diameter: 0.014"
8-9	Guide wire length	Character: 18, length (cm): 180
10	Flexibility	S: Standard
11	Languages used for labelling	M: Multi-language

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Hatagaya
Shibuya-ku
Tokyo
151-0072
Japan**

Crosswire NT Product Codes:

Outer Diameter (inch)	Product Code	Specifications	
		Length (cm)	Tip Shape
0.014"	CW*NA1418SM	180	Straight

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Runthrough NS

T W - □ □ □ □ □ □ □ □ □
 1 2 3 4 5 6 7 8 9 10 11 12

Character number	Denotation	
1-2	Product name	TW: TERUMO PTCA GUIDEWIRE
3	Destination	:- for domestic market/export
4	Shaft material	A: NiTi + SUS302 D: NiTi + SUS302 (for complex severely stenosed lesions)
5	Tip configuration	S: Straight
6	Outer diameter	4: 0.014"
7-8	Overall length (cm)	18: 180 30: 300
9	Tip flexibility support type	X: Extra Floppy, Normal Support F: Floppy, Normal Support I: Intermediate, Normal Support
10	Coil coating	H: Hydrophilic polymer (full coat) A: Hydrophilic polymer (silicone over 2mm in distal)
11	Number of product contained	Z: 1 product Blank: 5 products

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Date: **16 March 2016**

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44-1, 2-chome
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151-0072
Japan

Runthrough NS Product Codes:

Outer Diameter (inch)	Product Code	Specifications			Products per box (set/box)
		Length (cm)	Tip Flexibility	Coil Coating	
0.014"	TW-AS418FA	180	Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	5
	TW-AS418FAZ	180	Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	1
	TW-AS418XA	180	Extra Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	5
	TW-AS418XAZ	180	Extra Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	1
	TW-AS430XA	300	Extra Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	5
	TW-AS430XAZ	300	Extra Floppy	Hydrophilic coating (Silicone coating over distal 2mm)	1

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151-0072
Japan

Runthrough NS Product Codes (Continued):

Outer Diameter (inch)	Product Code	Specifications			
		Length (cm)	Tip Flexibility	Coil Coating	Products per box (set/box)
0.014"	TW-DS418IA	180	Intermediate	Hydrophilic coating (Silicone coating over distal 2mm)	5
	TW-DS418IAZ	180	Intermediate	Hydrophilic coating (Silicone coating over distal 2mm)	1
	TW-DS418FH	180	Floppy	Hydrophilic coating (Full)	5
	TW-DS418FHZ	180	Floppy	Hydrophilic coating (Full)	1

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151-0072
Japan

Certificate History

Date	Reference Number	Action
1 August 2014	10148394	Initial issue (transfer from another Notified Body)
16 March 2016	10159714	Change affecting Tyvek ®1073 B and Tyvek® 1059B packaging materials- all product codes are affected

First Issued: **01 August 2014**

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DECLARATION OF CONFORMITY

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

being the manufacturer of:

Runthrough NS

PTCA Guide Wire

Product : Cardiac Catheter Guide Wire

declare that the above products of **Class III** 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, 1(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, and by certification of Annex II excluding Section 4 (Certificate No.: CE 554734), and Annex II Section 4 (Certificate No.: CE 613749) under the supervision of BSI Product Services, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom, as Notified Body authorized by the United Kingdom Competent Authority and carrying the Notified Body No. 0086.


Authorized European Representative :

TERUMO EUROPE N.V.

Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, June 6, 2016
(place and date of issue)


Toshio Nakashima
General Manager
Quality Assurance Department
TERUMO CORPORATION

 **TERUMO®**

Appendix A - List of Code Number Structure

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

Character number	Character & Meaning	
1-2	Product name	TW : TERUMO PTCA GUIDEWIRE
3	Destination	— : for domestic market/export
4	Shaft material	A : Ni-Ti + SUS302 ; D : Ni-Ti + SUS302(for complex severely-stenosed lesions)
5	Tip configuration	S : Straight
6	Outer diameter	4 : 0.014"
7-8	Overall length (cm)	18 : 180 30 : 300
9	Tip flexibility, Support type	X : Extra Floppy·Normal Support F : Floppy·Normal Support I : Intermediate·Normal Support
10	Coil coating	H : Hydrophilic polymer (full coat) A : Hydrophilic polymer (silicone over 2 mm in distal)
11	Number of product contained	Z : 1 product Blank : 5 products