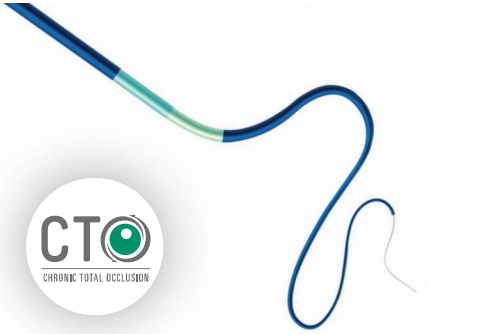
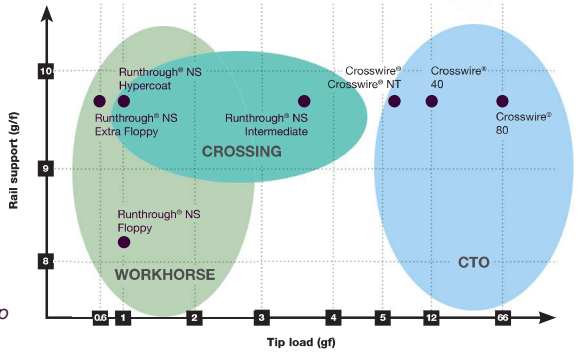
Runthrough® NS

PTCA Guidewire



Runthrough® NS is a PTCA guidewire intended to be used in interventional cardiology procedures.

Runthrough® NS is an innovative guidewire designed for workhorse lesions, as well as challenging lesions.



Guidewire segmentation map

Product Characteristics

- *Nitinol alloy distal core offers kink resistance and durability*
- *High strength stainless steel shaft designed to offer enhanced steerability and trackability*
- *Innovative DuoCore combines a great torque response with a durable tip*
- *Durable Terumo M Coat™ hydrophilic coating enables smooth manipulation*
- *The distal tip presents 2 mm silicone coating for an improved tactile feed-back*

General Specifications

Diameter	0.014" (0.36 mm)
Wire length	180 cm
Radiopaque length	3 cm
Distal shape	Straight
Distal coating	Hydrophilic
Proximal coating	PTFE

Item Specifications

Item	Clinical application	Tip load (gf)	Tip shaping part	Rail support	Coating	Distal tip coating	Item Reference Code
Runthrough® NS Extra Floppy	Workhorse	0.6 gf	10 mm	Stiffer	Hydrophilic	2 mm silicone	TW-AS418XA
Runthrough® NS Floppy	Workhorse	1 gf	10 mm	Moderate	Hydrophilic	2 mm silicone	TW-AS418FA
Runthrough® NS Hypercoat	Crossing	1 gf	14 mm	Stiffer	Enhanced hydrophilic	-	TW-DS418FH
Runthrough® NS Intermediate	Crossing	3.6 gf	10 mm	Stiffer	Hydrophilic	2 mm silicone	TW-DS418IA

Runthrough® NS Extension Wire	**Extension**	—	—	**TW-JJ415**

Please quote above item reference code when placing an order

IS616/15GB0616ITI

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:

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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-08-01** Date: **2019-07-26** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 613749

Issued To:

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

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

First Issued: **2014-08-01** Date: **2019-07-26** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 613749

Issued To:

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

Runthrough NS Product Codes:

Outer Diameter (inch)	Product Code	Specifications			
		Length (cm)	Tip Flexibility	Coil Coating	Products per box (set/box)
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

First Issued: **2014-08-01** Date: **2019-07-26** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 613749

Issued To:

Terumo Corporation
44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
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

First Issued: **2014-08-01** Date: **2019-07-26** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 613749

Issued To:

Terumo Corporation
44-1, 2-chome
Hatagaya
Shibuya-ku
Tokyo
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.
04 March 2019	7778938	Traceable to NB 0086.
Current	9731157	Certificate Renewal. Removed Crosswire and Crosswire NT.

First Issued: **2014-08-01** Date: **2019-07-26** Expiry Date: **2024-05-26**

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TERUMO

No. DOC-DQ010- 0767B

Rev.15

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 Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands, as Notified Body authorized by the Netherlands Competent Authority and carrying the Notified Body No. 2797.

Authorized European Representative:
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, July 30, 2019
(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

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

TERUMO

Appendix B - List of Product Code

Outer diameter (inch)	Product code	Specification			
		Length (cm)	Tip flexibility	Coil coating	Products per box (set/box)
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
	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

EC Certificate - Full Quality Assurance System

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

No. **CE 554734**

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

In respect of:

The Design and Manufacture of Balloon Dilatation Catheters, PTCA Guidewires, Angiographic Catheters, MicroGuide catheters, Coronary Imaging Catheters and coronary optical coherence tomography system.

Those aspects of Annex II related to securing and maintaining the sterility of the MDU cover, Extension Wires, and related accessories.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-10-30** Date: **2019-08-12** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 554734

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class III		
---	RyujinPlus	See CE 554735
---	Tazuna	See CE 554735
---	Hiryu	See CE 599214
---	RyujinPlus OTW	See CE 578316
---	Accuforce	See CE 608484
---	Ryurei	See CE 661655
---	Progreat	See CE 580672
---	Finecross MG	See CE 597867
---	Runthrough NS	See CE 613749
---	FastView	See CE 585621

First Issued: **2009-10-30** Date: **2019-08-12** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 554734

Issued To:

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

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1202	LUNAWAVE	---
Class Is		
MD 0106	RunthroughNS Extension wire	---
MD 0106	Fast View MDU cover	---

First Issued: **2009-10-30** Date: **2019-08-12** Expiry Date: **2024-05-26**

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 554734**
Date:	**2019-08-12**
Issued To:	**Terumo Corporation** **44-1, 2-chome** **Hatagaya** **Shibuya-ku** **Tokyo** **151-0072** **Japan**

Subcontractor:	**Service(s) supplied**
SUZUKI Co., Ltd. 2150-1 Ogawara Suzaka-shi Nagano 382-8588 Japan	**Manufacture**
Terumo Corporation Ashitaka Plant 150, Maimaigi-cho, Fujinomiya City, Shizuoka Prefecture 418-0015 Japan	**Design** **Development** **ETO Sterilization** **Manufacture**
Terumo Europe N.V. Interleuvenlaan 40 3001 Leuven Belgium	**EU Representative**

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By Royal Charter

EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 554734**
Date:	**2019-08-12**
Issued To:	**Terumo Corporation** **44-1, 2-chome** **Hatagaya** **Shibuya-ku** **Tokyo** **151-0072** **Japan**

Subcontractor:	**Service(s) supplied**
Ueda Japan Radio Co., Ltd. 2805-72 Nagase Ueda-shi Nagano 386-0407 Japan	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 554734**

Date: **2019-08-12**

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

Date	Reference Number	Action
30 October 2009	7443727	First Issue – Transfer from another Notified Body.
17 September 2010	7560390	Certificate renewal.
23 December 2011	7778290	Addition of "Angiographic Catheters" to the scope of the certificate. Additional service supplied for ETO sterilization at the Terumo Ashitaka Plant.
30 March 2012	7730762	Update to scope of certificate to add Coronary Imaging Catheters.
21 December 2012	7916383	Extension to scope to include LUNAWAVE.
18 April 2013	7948395 7959985	Optical Coherence Tomography System (LUNAWAVE) was introduced under 7916383 in Dec 2012. Brand name 'LUNAWAVE' has now been removed from scope. This does not affect the device types covered by the certificate. Extension of scope to include Class I sterile MDU cover and accessories.
4 June 2013	7974363	Extension to scope to include micro-guide catheters.
4 June 2014	8164373	Certificate renewal.
1 August 2014	8196034	Addition of "PTCA Guidewires" and "sterility of…Extension Wires" to the scope.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 554734**

Date: **2019-08-12**

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

Date	Reference Number	Action
27 April 2018	8942575	Added design and development service to Terumo Ashika Plant subcontractor.
04 March 2019	7778938	Traceable to NB 0086.
Current	9789827	Certificate Renewal. Added products table and subcontractors Ueda Japan Radio and SUZUKI.

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