

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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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Supplementary Information to CE 613749

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Runthrough NS

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 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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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

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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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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.

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