

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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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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