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No.DOC-DQ010- 0245/DOC- DC-0140969
Rev.24

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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:

RADIFOCUS Introducer II

Product :   Catheter Introducer

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

署名者:
hiroki sasagawa
署名者名: hiroki sasagawa
署名理由: この文書を承認する
署名時刻: 2024-07-25 | 4:42:35 午後 JST
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Tokyo,   2024-07-25
(place and date of issue)

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Hiroki Sasagawa
General Manager
Quality Assurance Department
TERUMO CORPORATION

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Appendix A - List of Code Number Structure

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1　2　3　4　5　6　7　8　9　10　11　12

Character number	Characters & Meaning
1, 2	Product name RS: Introducer kit RM: Introducer kit containing hydrophilic polymer-coated sheath.
3	Destination *: for export
4	Kit contents A　　: Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) B　　: Sheath, Dilator, Mini guide wire, (Guide inserter[*2]) C　　: Sheath, Dilator E　　: Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), (Guide inserter[*2]) G　　: Sheath, Dilator, Mini guide wire, Scalpel[*1] (Guide inserter[*2]) H　　: Dilator J　　: Sheath, Dilator, Scalpel[*1] K　　: Sheath, Dilator, Mini guide wire, Syringe, Entry needle (metallic needle), Scalpel[*1], (Guide inserter[*2]) L　　: Sheath, Dilator, Syringe, Entry needle (SurfloFlash), Scalpel[*1] M　　: Sheath, Dilator, Entry needle (SurfloFlash), Scalpel[*1] N　　: Sheath, Dilator, Mini guide wire, Syringe, Scalpel[*1], (Guide inserter[*2]) P　　: Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), (Guide inserter[*2]) Q　　: Dilator, Mini guide wire, (Guide inserter[*2]) R　　: Sheath, Dilator, Mini guide wire, Entry needle (metallic needle / Metallic Entry Needle improved product), (Guide inserter[*2]) S　　: Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) W　　: Mini guide wire [*1]: not contained in the export specifications [*2]: contained when the mini guide wire has an angled tip or a J tip.

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Character number	Characters & Meaning
5-6	Sheath Size (w/o hydrophilic polymer coating) Characters: 40 50 55 60 65 70 75 80 85 90 10 11 00 Size: 4.0 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 10.0 11.0 no sheath Sheath Size (with hydrophilic polymer coating) Characters: F4 F5 F6 F7 Size: 4.0 5.0 6.0 7.0
7	Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm) Standard Type (the items with their product code starting with RS*)

Standard Type (the items with their product code starting with RS*)

		Mini guide wire diameter/ Dilator inner diameter					Type of Surflo
		0.018"	0.021"	0.025"	0.035"	0.038"	
Type of scalpel and tray	b-type	A	D	G	K	N	Standard
	a-type	B	E	H	L	P	
	b-type	C	F	J	M	Q	With adapter
	a-type	V	W	X	Y	Z	
Entry needle size		22G×1"	22G×1"	20G×2"	18G×2 1/2"	16G×2 1/2"	
metallic needle size		---	---	---	18G×2 3/4"	18G×2 3/4"	

Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM):

		Mini guide wire diameter/ Dilator inner diameter					Type of Surflo
		0.018"	0.021"	0.025"	0.035"	0.038"	
Type of scalpel and tray	b-type	A	D	G	K	N	With adapter
	a-type	B	E	H	L	P	
	b-type	C	F	J	M	Q	Standard
	a-type	V	W	X	Y	Z	
Entry needle size		22G×1"	22G×1"	20G×2"	18G×2 1/2"	16G×2 1/2"	
metallic needle size		---	Metallic Entry Needle improved product 21G×1 2/5"	Metallic Entry Needle improved product 20G×1 2/5"	18G×2 3/4"	18G×2 3/4"	

Character number	Characters & Meaning
8-9	Length of sheath 05 ~: 50 mm ~

10	Type of mini guide wire
	  A: Plastic, Angled
	  B: Plastic, Angled, 4mm of tip cut
	  E: Straight E
	  F: Flex, Angled
	  H: Short tapered, short angle
	  J: Plastic, 3mm J
	  K: Stiff, Angled
	  M: Spring, J
	  N: No mini guide wire contained.
	  P: Spring, Straight
	  S: Plastic, Straight
	  V: Plastic, 1.5mm J-angle
	  Y: Flex, Straight

11	Packaging
	  Q: Tray package (Multi-language)
	  R: Pouch package (Multi-language)

12	Reserved
	  1: With scalpel.
	  5: Inner diameter of dilator at distal end: 0.038",
	     Outer diameter of mini guide wire: 0.035"
	  Z: Entry needle: 20Gx2"→20Gx1 1/4"
	     Length of mini guide wire: 80cm→45cm, scalpel contained.
	  W: Entry needle: 20Gx2"→20Gx1 1/4", scalpel contained.

Appendix A   - List of Code Number Structure

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

Character number	Characters & Meaning
1, 2	Product name RS: Introducer kit RM: Introducer kit containing hydrophilic polymer-coated sheath
3	Destination ＋/ ＊: Manufactured by TVC for worldwide excluding Japan
4	Kit contents A : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), Scalpel[*1], (Guide inserter[*2]) B : Sheath, Dilator, Mini guide wire, (Guide inserter[*2]) C : Sheath, Dilator R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle / Metallic Entry Needle improved product), (Guide inserter[*2]) *1: not contained in the export specification *2: contained when the mini guide wire has an angled tip or a J tip.

Character number 5-6:

Sheath Size (Fr) (w/o hydrophilic polymer coating)

Characters	40	50	60	70	80
Size	4.0	5.0	6.0	7.0	8.0

Sheath Size (Fr) (with hydrophilic polymer coating)

Characters	F5	F6
Size	5.0	6.0

Character number 7:

Mini guide wire OD, Dilator ID, Size of Enrty needle (length of projecting portion of dilator is 25mm)
Standard Type (the items with their product code starting with RS*)

	Mini guide wire diameter/ Dilator inner diameter					Type of Surflo
	0.018"	0.021"	0.025"	0.035"	0.038"	Standard
Type of scalpel and tray	A	D	G	K	N	
Entry needle size	---	---	20G×2"	18G×2 1/2"	16G×2 1/2"	
Metallic needle size	Metallic Entry Needle improved product 22G×1 2/5"	Metallic Entry Needle improved product 21G×1 2/5"	Metallic Entry Needle improved product 20G×1 2/5"	18G×2 3/4"	18G×2 3/4"	

	Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM*)				
		Mini guide wire diameter/ Dilator inner diameter			Type of Surflo
		0.021"	0.025"	0.035"	
	Type of scalpel and tray	---	G	---	With adapter
		F	J	M	Standard
	Entry needle size	---	20G×2"	---	
	Metallic needle size	Metallic Entry Needle improved product 21G×1 2/5"	Metallic Entry Needle improved product 20G×1 2/5"	---	

8-9	Length of sheath
	  00 : no sheath
	  05~ : 50mm~ ~

10	Type of mini guide wire
	  A: Plastic, Angled
	  M: Spring, J angled
	  N: No mini guide wire contained.
	  P: Spring, Straight
	  S: Plastic, Straight
	  H: Short tapered, short angle

11	Packaging
	  Q: Tray package (Multi-language #, Chinese)
	  R: Pouch package (Multi-language #, Chinese)

12	Reserved
	  1: With scalpel.
	  5: Inner diameter of dilator at distal end: 0.038",
	    Outer diameter of mini guide wire: 0.035"
	  Z: Entry needle: 20Gx2"→20Gx1 1/4"
	    Length of mini guide wire: 80cm→45cm, scalpel contained.
	  W: Entry needle: 20Gx2" →20Gx1 1/4" , scalpel contained.