

## 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

Tokyo, February 10, 2020  
(place and date of issue)

  
Toshio Nakashima  
General Manager  
Quality Assurance Department  
TERUMO CORPORATION

Appendix A - List of Code Number Structure

□ □ \* □ □ □ □ □ □ □ □ □ □  
 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* <sup>1</sup> , (Guide inserter* <sup>2</sup> ) B : Sheath, Dilator, Mini guide wire, (Guide inserter* <sup>2</sup> ) C : Sheath, Dilator E : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), (Guide inserter* <sup>2</sup> ) G : Sheath, Dilator, Mini guide wire, Scalpel* <sup>1</sup> (Guide inserter* <sup>2</sup> ) H : Dilator J : Sheath, Dilator, Scalpel* <sup>1</sup> K : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (metallic needle), Scalpel* <sup>1</sup> , (Guide inserter* <sup>2</sup> ) L : Sheath, Dilator, Syringe, Entry needle (SurfloFlash), Scalpel* <sup>1</sup> M : Sheath, Dilator, Entry needle (SurfloFlash), Scalpel* <sup>1</sup> N : Sheath, Dilator, Mini guide wire, Syringe, Scalpel* <sup>1</sup> , (Guide inserter* <sup>2</sup> ) P : Sheath, Dilator, Mini guide wire, Syringe, Entry needle (SurfloFlash), (Guide inserter* <sup>2</sup> ) Q : Dilator, Mini guide wire, (Guide inserter* <sup>2</sup> ) R : Sheath, Dilator, Mini guide wire, Entry needle (metallic needle / Metallic Entry Needle improved product), (Guide inserter* <sup>2</sup> ) S : Sheath, Dilator, Mini guide wire, Entry needle (SurfloFlash), Scalpel* <sup>1</sup> , (Guide inserter* <sup>2</sup> ) W : Mini guide wire * <sup>1</sup> : not contained in the export specifications * <sup>2</sup> : contained when the mini guide wire has an angled tip or a J tip.

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5-6	Sheath Size (w/o hydrophilic polymer coating) Characters: 40 45 50 55 60 65 70 75 80 85 90 10 11 00 Size: 4.0 4.5 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 Entry needle (length of projecting portion of dilator is 25mm) Standard Type (the items with their product code starting with RS*) <table border="1" data-bbox="491 712 1449 1104"> <thead> <tr> <th colspan="2" rowspan="2"></th> <th colspan="5">Mini guide wire diameter/ Dilator inner diameter</th> <th rowspan="2">Type of Surflo</th> </tr> <tr> <th>0.018"</th> <th>0.021"</th> <th>0.025"</th> <th>0.035"</th> <th>0.038"</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Type of scalpel and tray</td> <td>a-type</td> <td>A</td> <td>D</td> <td>G</td> <td>K</td> <td>N</td> <td rowspan="2">Standard</td> </tr> <tr> <td>b-type</td> <td>B</td> <td>E</td> <td>H</td> <td>L</td> <td>P</td> </tr> <tr> <td>a-type</td> <td>C</td> <td>F</td> <td>J</td> <td>M</td> <td>Q</td> <td rowspan="2">With adapter</td> </tr> <tr> <td>b-type</td> <td>V</td> <td>W</td> <td>X</td> <td>Y</td> <td>Z</td> </tr> <tr> <td colspan="2">Entry needle size</td> <td>22G×1"</td> <td>22G×1"</td> <td>20G×2"</td> <td>18G×2 1/2"</td> <td>16G×2 1/2"</td> <td rowspan="2"></td> </tr> <tr> <td colspan="2">metallic needle size</td> <td>---</td> <td>---</td> <td>---</td> <td>18G×2 3/4"</td> <td>18G×2 3/4"</td> </tr> </tbody> </table> <p>*Kit containing a hydrophilic polymer-coated sheath (the items with their product code starting with RM*):</p> <table border="1" data-bbox="387 1171 1449 1675"> <thead> <tr> <th colspan="2" rowspan="2"></th> <th colspan="5">Mini guide wire diameter/ Dilator inner diameter</th> <th rowspan="2">Type of Surflo</th> </tr> <tr> <th>0.018"</th> <th>0.021"</th> <th>0.025"</th> <th>0.035"</th> <th>0.038"</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Type of scalpel and tray</td> <td>a-type</td> <td>A</td> <td>D</td> <td>G</td> <td>K</td> <td>N</td> <td rowspan="2">With adapter</td> </tr> <tr> <td>b-type</td> <td>B</td> <td>E</td> <td>H</td> <td>L</td> <td>P</td> </tr> <tr> <td>a-type</td> <td>C</td> <td>F</td> <td>J</td> <td>M</td> <td>Q</td> <td rowspan="2">Standard</td> </tr> <tr> <td>b-type</td> <td>V</td> <td>W</td> <td>X</td> <td>Y</td> <td>Z</td> </tr> <tr> <td colspan="2">Entry needle size</td> <td>22G×1"</td> <td>22G×1"</td> <td>20G×2"</td> <td>18G×2 1/2"</td> <td>16G×2 1/2"</td> <td rowspan="2"></td> </tr> <tr> <td colspan="2">metallic needle size</td> <td>---</td> <td>Metallic Entry Needle improved product 21G×1 2/5"</td> <td>Metallic Entry Needle improved product 20G×1 2/5"</td> <td>18G×2 3/4"</td> <td>18G×2 3/4"</td> </tr> </tbody> </table>			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	a-type	A	D	G	K	N	Standard	b-type	B	E	H	L	P	a-type	C	F	J	M	Q	With adapter	b-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"			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	a-type	A	D	G	K	N	With adapter	b-type	B	E	H	L	P	a-type	C	F	J	M	Q	Standard	b-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"
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8-9	Length of sheath 00 : no sheath 05~ : 50mm~
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: 20Gx1 1/4", scalpel contained.

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