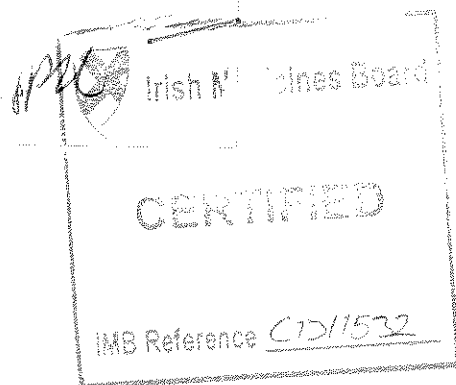




IRISH MEDICINES BOARD



18 June 2013

## CERTIFICATE OF FREE SALE

### To Whom It May Concern

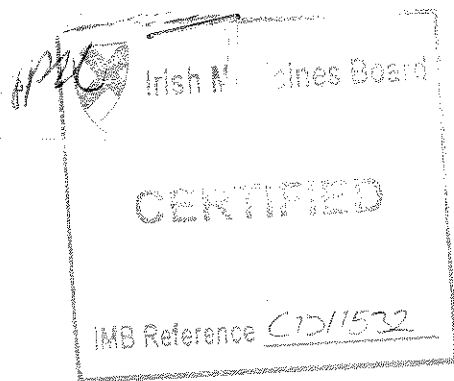
The Irish Medicines Board hereby certifies that:

- 1) When the general medical devices in the attached schedule bear the words 'Made in Ireland' on their label, they are manufactured in Ireland by Lake Region Medical Limited, Butlersland, New Ross, Co. Wexford. The Authorised Representative in Europe is Boston Scientific International S.A., European Headquarters, 55 avenue des Champs Pierreux, TSA 51101, 92729 Nanterre Cedex, France. Manufacturer (as defined in the Medical Devices Directive 93/42/EEC) is Lake Region Medical, 340 Lake Hazeltine Drive, Chaska, MN 55318 USA.
- 2) The general medical devices specified in the attached schedule are CE marked in accordance with the European Communities (Medical Devices) Regulations, 1994 (which transposed the Medical Devices Directive 93/42/EEC into Irish Law) and may be marketed and sold in Ireland.
- 3) Exportation of the general medical devices listed in the attached schedule is not prohibited.
- 4) The granting of this certificate is based on the information available to the Irish Medicines Board on the date of issue of the certificate.

**Issued To:** Lake Region Medical Limited  
Butlersland  
New Ross  
Co. Wexford

**Expiry Date:** 18 June 2018

  
**Patrick Keating**  
Compliance Department  
Irish Medicines Board



18 June 2013

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**Irish Medicines Board**

Bord Leigheasra na hÉireann



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Irish Medicines Board

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**APOSTILLE**  
(Convention de La Haye du 5 octobre 1961)

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<b>This public document</b> Le présent acte public / El presente documento público			
<b>2. has been signed by</b> a été signé par ha sido firmado por		Mr. Patrick Keating	
<b>3. acting in the capacity of</b> agissant en qualité de quien actúa en calidad de		Irish Medicines Board	
<b>4. bears the seal / stamp of</b> est revêtu du sceau / timbre de y está revestido del sello / timbre de		-----	
<b>Certified</b> Attesté / Certificado			
<b>5. at</b> à / en	Dublin	<b>6. the</b> le / el día	17/07/2013
<b>7. by</b> par / por	Department of Foreign Affairs and Trade		
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# MEDICAL DEVICE SCHEDULE

Item Number/Product Code		Description of Device
		Starter Guidewire
M001491001	49-100	Starter 150 cm Fixed Core Straight
M001491011	49-101	Starter 150 cm Fixed Core Straight
M001491021	49-102	Starter 150 cm Fixed Core Straight
M001491031	49-103	Starter 260 cm Fixed Core Straight
M001492001	49-200	Starter 150 cm Fixed Core Straight
M001492011	49-201	Starter 40 cm Fixed Core Straight
M001492021	49-202	Starter 100 cm Fixed Core Straight
M001492031	49-203	Starter 125 cm Fixed Core Straight
M001492051	49-205	Starter 40 cm Fixed Core Straight
M001492061	49-206	Starter 150 cm Fixed Core Straight
M001492071	49-207	Starter 40 cm Fixed Core Straight
M001492081	49-208	Starter 150 cm Fixed Core Straight
M001492091	49-209	Starter 40 cm Fixed Core Straight
M001492101	49-210	Starter 100 cm Fixed Core Straight
M001492111	49-211	Starter 125 cm Fixed Core Straight
M001492121	49-212	Starter 180 cm Fixed Core Straight
M001492131	49-213	Starter 260 cm Fixed Core Straight
M001492141	49-214	Starter 100 cm Fixed Core Straight
M001492151	49-215	Starter 125 cm Fixed Core Straight
M001492311	49-231	Starter 80 cm Fixed Core Straight
M001492501	49-250	Starter 150 cm Fixed Core Straight
M001492511	49-251	Starter 150 cm Fixed Core Uncoated Straight
M001491101	49-110	Starter 150 cm Moveable Core Straight
M001491111	49-111	Starter 150 cm Moveable Core Straight
M001492351	49-235	Starter 150 cm Moveable Core Coated Straight
M001491151	49-115	Starter 150 cm J Curved Fixed Core
M001491161	49-116	Starter 150 cm J Curved Fixed Core
M001491171	49-117	Starter 125 cm J Curved Fixed Core
M001491181	49-118	Starter 150 cm J Curved Fixed Core
M001491191	49-119	Starter 150 cm J Curved Fixed Core
M001491201	49-120	Starter 180 cm J Curved Fixed Core
M001491211	49-121	Starter 260 cm J Curved Fixed Core
M001491221	49-122	Starter 150 cm J Curved Fixed Core
M001491231	49-123	Starter 150 cm J Curved Fixed Core
M001492201	49-220	Starter 150 cm J Curved Fixed Core
M001492211	49-221	Starter 150 cm J Curved Fixed Core
M001492221	49-222	Starter 40 cm J Curved Fixed Core
M001492231	49-223	Starter 100 cm J Curved Fixed Core
M001492241	49-224	Starter 150 cm J Curved Fixed Core
M001492251	49-225	Starter 150 cm J Curved Fixed Core
M001492261	49-226	Starter 180 cm J Curved Fixed Core
M001492271	49-227	Starter 150 cm J Curved Fixed Core
M001492281	49-228	Starter 150 cm J Curved Fixed Core
M001492291	49-229	Starter 150 cm J Curved Fixed Core
M001492301	49-230	Starter 80 cm J Curved Fixed Core
M001491301	49-130	Starter 150 cm J Movable Core
M001491311	49-131	Starter 125 cm J Movable Core
M001491321	49-132	Starter 150 cm J Movable Core
M001491331	49-133	Starter 150 cm J Movable Core

## MEDICAL DEVICE SCHEDULE

Item Number/Product Code	Description of Device
M001491341	49-134 Starter 260 cm J Movable Core
M001491351	49-135 Starter 150 cm J Movable Core
M001491361	49-136 Starter 150 cm J Movable Core
M001491371	49-137 Starter 150 cm J Movable Core
M001491381	49-138 Starter 150 cm J Movable Core Tapered
M001491391	49-139 Starter 150 cm J Movable Core Tapered
M001491451	49-145 Starter 150 cm Bentson Straight
M001491461	49-146 Starter 150 cm Bentson Straight
M001491471	49-147 Starter 180 cm Bentson Straight
M001491481	49-148 Starter 260 cm Bentson Straight
M001491501	49-150 Starter 150 cm Newton 10cm Core Tapered Straight
M001491511	49-151 Starter 150 cm Newton 15cm Core Tapered Straight
M001491521	49-152 Starter 150 cm Newton J
M001491531	49-153 Starter 150 cm Newton J
M001492361	49-236 Starter 150 cm Newton Straight
M001492371	49-237 Starter 150 cm Newton J
M001492381	49-238 Starter 150 cm Newton J
M001491551	49-155 Starter 150 cm Rosen J
M001491561	49-156 Starter 180 cm Rosen J
M001491571	49-157 Starter 260 cm Rosen J