



19 May 2015

CERTIFICATE OF FREE SALE

To Whom It May Concern

The Health Products Regulatory Authority 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 Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland. The Authorised Representative in Europe is Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland. Legal Manufacturer (as defined by the Medical Devices Directive 93/42/EEC) is Boston Scientific Corporation, 300 Boston Scientific Way, Marlborough, MA 01752 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 Health Products Regulatory Authority on the date of issue of the certificate.

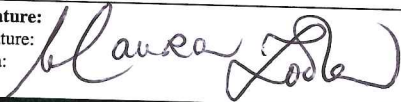
Issued To: Boston Scientific Limited
Ballybrit Business Park
Galway
Ireland

Expiry Date: 19 May 2020


Patrick Keating
Compliance Department
Health Products Regulatory Authority
CFS007113

Page 1 of 2



APOSTILLE (Convention de La Haye du 5 octobre 1961)			
1. Country: Pays/País:		IRELAND	
This public document Le présent acte public / El presente documento público			
2. has been signed by a été signé par ha sido firmado por		Mr. Patrick Keating	
3. acting in the capacity of agissant en qualité de quien actúa en calidad de		Health Products Regulatory Authority	
4. bears the seal / stamp of est revêtu du sceau / timbre de y está revestido del sello / timbre de		-----	
Certified Attesté / Certificado			
5. at à / en	Dublin	6. the le / el día	28/05/2015
7. by par / por	Department of Foreign Affairs and Trade		
8. No sous no bajo el número	1842882015		
9. Seal / stamp: Sceau / timbre: Sello / timbre:	10. Signature: Signature: Firma: 		

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document and, where appropriate, the identity of the seal or stamp which the public document bears. This Apostille does not certify the content of the document for which it was issued. To verify the issuance of this Apostille, see www.authentications.dfat.ie



MEDICAL DEVICE SCHEDULE

Item Number/Product	Description of Device
UPN: H749LTV230 GTIN: 08714729845140	Lotus™ Valve System 23mm Lotus Valve System 23mm Lotus Valve System
UPN: H749LTV250 GTIN: 08714729863168	25mm Lotus Valve System 25mm Lotus Valve System
UPN: H749LTV270 GTIN: 08714729845157	27mm Lotus Valve System 27mm Lotus Valve System