



Boston Scientific Corporation
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EC DECLARATION OF CONFORMITY

Legal Manufacturer: Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

Manufacturing Site: Boston Scientific Corporation
302 Parkway
Global Park, Heredia
COSTA RICA

European Representative: Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

Product: **V-14™ Control Wire™ Guidewire with
ICE™ Hydrophilic Coating**
Technical File: 90717587
See Attachment A for Model Designations.

Classification: Class IIa, Rule 6 according to Annex IX of the
MDD.

Notified Body: **BSI**
Kitemark Court
Davy Avenue, Knowlhill
Milton Keynes, MK5 8PP
UNITED KINGDOM
Identification Number: 0086
BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP, Amsterdam
THE NETHERLANDS
Identification Number: 2797

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Certificates	
Certificate Name	Certificate Number
BSI Full Quality Assurance System Certificate*	CE 616288
BSI Quality Management System Certificate – EN ISO 13485:2016	MD 670368

(* This certificate was originally issued by BSI UK (Notified Body #0086) and was migrated to BSI Group The Netherlands B.V. (Notified Body #2797) on 5-March-2019

All BSC SAP manufactured products are released per *Corp Form Product Shipment Release Requirements, 90213259*.

We declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices as amended by Directive 2007/47/EC. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal Manufacturer.

Signature, Date of Issue:

Name: Hollie Beckord, as designee for Brandon Erickson, Director, Quality Assurance
Title: Manager, Quality

Signature: Hollie Beckord 25 Mar 2019
Date

Name: Candice R. Burns
Title: Vice President, Regulatory Affairs
Peripheral Interventions

Signature: Candice R. Burns 25 Mar 2019
Date

(This is not an effective version)

ATTACHMENT A

Model Designation Summary

UPN	GTIN	Device Length	Taper Length	Tip Shape
H74939216718210	08714729799207	0.014 in x 182 cm	Short	Straight
H74939216718220	08714729799214	0.014 in x 182 cm	Short	Angled
H74939216730010	08714729799221	0.014 in x 300 cm	Short	Straight
H74939216730020	08714729799238	0.014 in x 300 cm	Short	Angled
H74939216918210	08714729799245	0.014 in x 182 cm	Long	Straight
H74939216918220	08714729799252	0.014 in x 182 cm	Long	Angled
H74939216930010	08714729799269	0.014 in x 300 cm	Long	Straight
H74939216930020	08714729799276	0.014 in x 300 cm	Long	Angled

(This is not an effective revision)

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