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EC DECLARATION OF CONFORMITY

Legal Manufacturer: And SRN #	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA SRN: US-MF-000004702
Design Site:	Boston Scientific Corporation 302 Parkway Global Park Heredia Costa Rica
Manufacturing Site(s):	Boston Scientific Corporation 302 Parkway Global Park Heredia Costa Rica
EU Authorized Representative: And SRN #	Boston Scientific Limited Ballybrit Business Park Galway IRELAND SRN: IE-AR-000003840
Product(s):	V-18™ Control Wire™ Tech Doc File: 92778365, Regis 125155 BUDI-DI: 0191506000000000000284NA Model designation list is provided in Appendix A.
Risk Classification:	The V-18™ Control Wire™ is classified as Class IIa in conformity with Annex VIII, Chapter III Rule 7 of the EU Medical Device Regulation 2017/745.

Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam NETHERLANDS Identification Number: 2797
Conformity Assessment Path:	MDR 2017/745 Annex IX: Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation.
Intended Purpose:	The V-18 Control Wire Guidewire with ICE Hydrophilic Coating is available in 110 cm, 150 cm, 200 cm and 300 cm lengths. The wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. This device is intended for peripheral use only. A torque device (pin vise) is included with each wire to facilitate directional manipulation of the guidewire. The 110 cm V-18 Control Wire Guidewire with ICE Hydrophilic Coating is intended for general intravascular use including the placement of PTA balloon catheters requiring an 0.018 in (≤ 0.47 mm) guidewire in hemodialysis AV access procedures. The 150 cm, 200 cm and 300 cm V-18 Control Wire Guidewire with ICE Hydrophilic Coating are intended for general intravascular use.

Certificates	
Certificate Name	Certificate Numbers
BSI EU Quality Management System Certification	MDR 737710
BSI Quality Management Certificate - EN ISO/ISO 13485:2016	MD 670368

Common Specifications: Not Applicable
Additional EU Legislation Requiring Declarations of Conformity: Not Applicable

All BSC manufactured products are released per Global SOP Active Release 92138090 which provides the minimum requirements for active release of product which are distributed by Boston Scientific Corporation (BSC).

We declare that the product(s) identified are in conformance with all relevant provisions of the European Medical Device Regulation, MDR 2017/745, and with any other relevant Union legislation that provides for the issuance of an EU declaration of conformity. This EU Declaration of Conformity and all supporting information is issued and retained under the sole responsibility of Boston Scientific Corporation.

Signature, Date, Place of Issue:

Name: Barbara A Gerard
Title: Director, Quality

Signature:  Electronically signed by: Barb Gerard
Reason: I am the Approver
Date: Jun 26, 2024 11:24 CDT

Captured Electronically

Date USA

Name: Jenny Jiang
Title: Director, Regulatory Affairs

Signature:  Electronically signed by: Jenny Jiang
Reason: I am the Approver
Date: Jun 26, 2024 13:58 CDT

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Date USA

Appendix A: Model Designation List

Model Designations	
Catalogue/ REF#	Description
M001468480	V-18, 110cm, 8cm POLY TIP
M001468500	V-18, 150cm, 8cm POLY TIP
M001468520	V-18, 200cm, 8cm POLY TIP
M001468540	V-18, 300cm, 8cm POLY TIP
M001468560	V-18, 150cm, 12cm POLY TIP
M001468580	V-18, 200cm, 12cm, POLY TIP
M001468600	V-18, 300cm, 12cm POLY TIP








92798562 V-18 ControlWire Guidewire EU MDR DoC


Final Audit Report


2024-06-26


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