



Boston Scientific Corporation
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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 Two Scimed Place Maple Grove, MN 55311 USA
Manufacturing Site(s):	Boston Scientific Corporation 4100 Hamline Ave. N. St. Paul, MN 55112 USA
EU Authorized Representative: And SRN#	Boston Scientific Limited Ballybrit Business Park Galway IRELAND SRN: IE-AR-000003840
Product(s):	AVVIGO™ Guidance System II AVVIGO™+ Multi-Modality Guidance System Tech Doc File: 92938935 BUDI-DI: 01915060000000000000269NE
Risk Classification:	The AVVIGO™+ Multi-Modality Guidance System and AVVIGO Guidance System II Physiology and IVUS modalities are classified as Class IIa, Active Device, Rule 10 and 11, Annex VIII, Chapter III

Boston Scientific
EC Declaration of Conformity
AVVIGO Guidance Systems
92749565 Revision G

	The MDU5 Plus, and FFR Link accessories are Class IIa, Active Device, Rule 10, Annex VIII, Chapter III
Notified Body:	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem NETHERLANDS Identification Number: 0344
Conformity Assessment Path:	MDR 2017/745 Annex IX: Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation.
Intended Purpose:	<p>The IVUS modality of the System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are stable and are candidates for transluminal interventional procedures such as angioplasty and atherectomy.</p> <p>FFR and DFR™ are intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. FFR and DFR are indicated to provide hemodynamic information for use in the diagnosis and treatment of stable patients with intermediate-grade stenosis that undergo measurement of physiological parameters.</p> <p>The Imaging Catheters generate ultrasound images and are intended for ultrasound examination of vascular and cardiac pathology. Boston Scientific manufactures a wide variety of catheters for different applications. The recommended use of each of these catheters may vary depending on the size and type of the catheter. Please refer to the Imaging Catheter Instructions for Use, packaged with each catheter.</p>

	<p>Indications for Auto Pullback Use (IVUS Only)</p> <p>Automatic Pullback is indicated when the following occurs:</p> <ul style="list-style-type: none"> The physician/operator wants to standardize the method in which intravascular ultrasound images are obtained and documented: procedure-to-procedure, operator-to-operator. The physician/operator wants to make linear distance determinations post-procedurally, which requires the imaging core of a catheter to be pulled back at a known uniform speed. <p>Two-dimensional, longitudinal reconstruction of the anatomy is desired.</p>
Date of Initial DoC Sign-Off under MDR	15 Feb 2023

Model Designations		
Finished Goods Number (e.g., UPN)	Description	Contents
H7492493320C0	AVVIGO + Mobile System, EU + ROW	AVVIGO+ Tablet, V4 Acquisition PC and Power Supply, Isolation Station Transformer, AVVIGO+ Display Adapters, AVVIGO+ Zipper Cable Sleeve and Straps, AVVIGO PC Power Cords and Ethernet Kit, Pole Docking Station, AVVIGO Mobile Display Monitor with Power Supply, AVVIGO Mobile Pole, AVVIGO Mobile Platform, AVVIGO Mobile MDU Bin, AVVIGO V4 Acq PC and Power Supply Clamp, AVVIGO Mouse and Keyboard Kit, AVVIGO Mobile Cable Clips and Monitor Mount Kit, Do Not Push Sticker, Branding Sticker, AVVIGO+ HDMI Splitter Kit, 15ft ISOX Power Cable CCEE 7/7 EU

Model Designations		
Finished Goods Number (e.g., UPN)	Description	Contents
H7492493320CR0	AVVIGO+ Mobile System - Refurbished, EU+ROW	AVVIGO+ Tablet, V4 Acquisition PC and Power Supply, Isolation Station Transformer, AVVIGO+ Display Adapters, AVVIGO+ Zipper Cable Sleeve and Straps, AVVIGO PC Power Cords and Ethernet Kit, Pole Docking Station, AVVIGO Mobile Display Monitor with Power Supply, AVVIGO Mobile Pole, AVVIGO Mobile Platform, AVVIGO Mobile MDU Bin, AVVIGO V4 Acq PC and Power Supply Clamp, AVVIGO Mouse and Keyboard Kit, AVVIGO Mobile Cable Clips and Monitor Mount Kit, Do Not Push Sticker, Branding Sticker, AVVIGO+ HDMI Splitter Kit, 15ft ISOX Power Cable CCEE 7/7 EU
H7492493320D0	AVVIGO+ Mobile System – EVAL, EU+ROW	AVVIGO+ Tablet, V4 Acquisition PC and Power Supply, Isolation Station Transformer, AVVIGO+ Display Adapters, AVVIGO+ Zipper Cable Sleeve and Straps, AVVIGO PC Power Cords and Ethernet Kit, Pole Docking Station, AVVIGO Mobile Display Monitor with Power Supply, AVVIGO Mobile Pole, AVVIGO Mobile Platform, AVVIGO Mobile MDU Bin, AVVIGO V4 Acq PC and Power Supply Clamp, AVVIGO Mouse and Keyboard Kit, AVVIGO Mobile Cable Clips and Monitor Mount Kit, Do Not Push Sticker, Branding Sticker, AVVIGO+ HDMI Splitter Kit, 15ft ISOX Power Cable CCEE 7/7 EU, MDU5 Plus Motor Drive, Permanent Sled, FFR Link, SPM mounting kit
H7492493320I0	AVVIGO+ Integrated system, EU + ROW	AVVIGO+ Tablet PC, V4 Acquisition PC and Power Supply, Isolation Station Transformer, AVVIGO+ Display Adapters, AVVIGO+ Zipper Cable Sleeve and Straps, AVVIGO PC Power Cords and Ethernet Kit, Desktop Docking Station, Installed PC to Xformer

Model Designations		
Finished Goods Number (e.g., UPN)	Description	Contents
		Power Adapter, AVVIGO Mouse and Keyboard Kit, 15ft ISOX Power Cable CCEE 7/7 EU
H7492493320IR0	AVVIGO+ Integrated system - Refurbished, EU+ROW	AVVIGO+ Tablet PC, V4 Acquisition PC and Power Supply, Isolation Station Transformer, AVVIGO+ Display Adapters, AVVIGO+ Zipper Cable Sleeve and Straps, AVVIGO PC Power Cords and Ethernet Kit, Desktop Docking Station, Installed PC to Xformer Power Adapter, AVVIGO Mouse and Keyboard Kit, 15ft ISOX Power Cable CCEE 7/7 EU
H749009883C0	AVVIGO Guidance System II Mobile EU	AVVIGO 2.0 Tablet, Pole Docking Station, Stylus Pen, V3 Acq PC, Isolation Station Transformer, AVVIGO Mouse and Keyboard Kit, PC Power Cords and Ethernet Kit, Secondary Display Cords and Sleeve, Mobile Display Monitor with Power Supply, Mobile Pole, Mobile Platform, Mobile Cable Clips and Monitor Mount Kit, Mobile MDU and Acq PC Mount Kit
H749009883CR0	AVVIGO Guidance System II Mobile Refurb EU	AVVIGO 2.0 Tablet (Refurbished Unit), Pole Docking Station, Stylus Pen, V3 Acq PC, Isolation Station Transformer, AVVIGO Mouse and Keyboard Kit, PC Power Cords and Ethernet Kit, Secondary Display Cords and Sleeve, Mobile Display Monitor with Power Supply, Mobile Pole, Mobile Platform, Mobile Cable Clips and Monitor Mount Kit, Mobile MDU and Acq PC Mount Kit
H749009883I0	AVVIGO Guidance System II Integrated EU	AVVIGO 2.0 Tablet, Stylus Pen, Desktop Docking Station, Generic Power Supply, V3 Acq PC, Isolation Transformer, AVVIGO Mouse and Keyboard Kit, Secondary Display Cords and Sleeve
H749009883IR0	AVVIGO Guidance System II Integrated	AVVIGO 2.0 Tablet (Refurbished Unit), Stylus Pen, Desktop Docking Station, Generic Power

Model Designations		
Finished Goods Number (e.g., UPN)	Description	Contents
	Refurb EU	Supply, V3 Acq PC, Isolation Transformer, AVVIGO Mouse and Keyboard Kit, Secondary Display Cords and Sleeve
H749009883CD0	AVVIGO Guidance System II – Eval, EU	AVVIGO 2.0 Tablet, Pole Docking Station, Stylus Pen, V3 Acq PC, Isolation Station Transformer, AVVIGO Mouse and Keyboard Kit, PC Power Cords and Ethernet Kit, Secondary Display Cords and Sleeve, Mobile Display Monitor with Power Supply, Mobile Pole, Mobile Platform, Mobile Cable Clips and Monitor Mount Kit, Mobile MDU and Acq PC Mount Kit, Pelican Case
H7492493321I0	AVVIGO Guidance System II to AVVIGO+ integrated upgrade kit EU+ROW	AVVIGO+ Zipper Cable Sleeve and Straps, AVVIGO+ Tablet, V4 Acquisition PC and Power Supply
H7492493321C0	AVVIGO Guidance System II to AVVIGO+ mobile upgrade kit EU+ROW	AVVIGO+ Tablet, V4 Acquisition PC and Power Supply, AVVIGO+ Zipper Cable Sleeve and Straps, AVVIGO AQC PC and Power Supply Clamp, Do Not Push Sticker, Branding Sticker, AVVIGO+ Mobile Splitter Kit, AVVIGO+ Display Adapters
H749MDU5PLUSF0	MDU5 Motordrive Unit	MDU5 Plus Motordrive Unit
H749MDU5PLUSFR0	MDU5 Motordrive Unit - Refurbished	MDU5 Plus Motordrive Unit (refurbished)
H749MDU5PLUSFH0	MDU5 Motordrive Unit – Hospital Owned Repair	MDU5 Plus Motordrive Unit
H749MDU5PLUS0	MDU5 PLUS Motordrive Unit	MDU5 Plus Motor Drive Unit

Model Designations		
Finished Goods Number (e.g., UPN)	Description	Contents
H749MDU5PLUSR0	MDU5 PLUS Motordrive Unit- Repair	MDU5 Plus Motor Drive Unit (Refurbished Unit)
H749MDU5PLUSRR0	MDU5 PLUS Motordrive Unit – ROHS Repair	MDU5 Plus Motor Drive Unit
H7495551000	FFR Signal Processing Module	FFR Link
H749555100R0	FFR Signal Processing Module -	FFR Link (Refurbished)
H749555100H0	FFR Signal Processing Module – Hospital owned	FFR Link
H749555100D0	FFR Signal Processing Module - Eval	FFR Link
H7490097650	AVVIGO Guidance System II Tablet	Tablet
H749009765R0	AVVIGO Guidance System II Tablet - (Refurbished)	Tablet
H74924930220	AVVIGO+ TABLET – New, Global	AVVIGO+ Tablet PC
H7492493022R0	AVVIGO+ TABLET – REFURB, Global	AVVIGO+ Tablet PC (Refurbished)

Certificates	
Certificate Name	Certificate Numbers
DEKRA Certification EU Quality Management System Certification.	3830129CE01
DEKRA Certification Management System Certificate - EN ISO/ISO 13485:2016	3818536

Contract Manufacturer Certificate(s)	
Certificate Name	Certificate Number
N/A	N/A

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

The product described herein is in conformity with the relevant Union harmonization legislation identified below, and the document referenced includes the standards and technical specifications applied:	
Directive	Document ID Number
Directive 2015/863/EU (RoHS)	92791828 (AVVIGO II) 97048241 (AVVIGO+)
Directive 2014/53/EU (RED)	51655314 (AVVIGO II) 51162859 (AVVIGO+) 92110817 (FFR Link)
Directive 2006/42/EC (Machinery)	92938804

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: Erin Farrens
Title: Senior Director Quality Assurance

Signature:  Electronically signed by: Erin Hyndman-Farrens
Reason: I am the Approver
Date: Mar 4, 2024 10:11 CST

Date USA

Name: Eric Elliott
Title: Director Regulatory Affairs

Signature:  Electronically signed by: Eric Elliott
Reason: I am the Approver
Date: Mar 4, 2024 10:16 CST

Date USA

Name: Kevin Bloms
Title: Director Research and Development

Signature:  Electronically signed by: Kevin Bloms
Reason: I am the Approver
Date: Mar 4, 2024 09:49 CST

Date USA

Note: For documents translated into a language other than English, refer to signatures and dates of issue from the accompanying English version.

Boston Scientific
EC Declaration of Conformity
AVVIGO Guidance Systems
92749565 Revision G








92749565 DOC AVVIGO Guidance Systems MDR DOC (Rev G blacklines)

Final Audit Report

2024-03-04

Created:	2024-03-04
By:	Kevin Catalano (Kevin.Catalano@bsci.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAmXnl5eNOfB3HbqTGNEyxUb9EZLD7HSxs
Number of Documents:	1
Document page count:	9
Number of supporting files:	0
Supporting files page count:	0

"92749565 DOC AVVIGO Guidance Systems MDR DOC (Rev G blacklines)" History

-  Document created by Kevin Catalano (Kevin.Catalano@bsci.com)
2024-03-04 - 3:41:38 PM GMT
-  Document emailed to kevin.bloms@bsci.com for signature
2024-03-04 - 3:44:06 PM GMT
-  Document emailed to Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com) for signature
2024-03-04 - 3:44:06 PM GMT
-  Document emailed to Eric Elliott (Eric.Elliott@bsci.com) for signature
2024-03-04 - 3:44:07 PM GMT
-  Email viewed by kevin.bloms@bsci.com
2024-03-04 - 3:46:53 PM GMT
-  kevin.bloms@bsci.com authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
2024-03-04 - 3:48:16 PM GMT
-  Signer kevin.bloms@bsci.com entered name at signing as Kevin Bloms
2024-03-04 - 3:49:13 PM GMT

✓ kevin.bloms@bsci.com authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2024-03-04 - 3:49:14 PM GMT

✓ Kevin Bloms (kevin.bloms@bsci.com) has agreed to the terms of use and to do business electronically with Boston Scientific

2024-03-04 - 3:49:15 PM GMT

✓ Document e-signed by Kevin Bloms (kevin.bloms@bsci.com)

Signing reason: I am the Approver

Signature Date: 2024-03-04 - 3:49:15 PM GMT - Time Source: server

✓ Email viewed by Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com)

2024-03-04 - 4:10:12 PM GMT

✓ Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-03-04 - 4:10:49 PM GMT

✓ Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com) has agreed to the terms of use and to do business electronically with Boston Scientific

2024-03-04 - 4:11:28 PM GMT

✓ Document e-signed by Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com)

Signing reason: I am the Approver

Signature Date: 2024-03-04 - 4:11:28 PM GMT - Time Source: server

✓ Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2024-03-04 - 4:11:28 PM GMT

✓ Email viewed by Eric Elliott (Eric.Elliott@bsci.com)

2024-03-04 - 4:15:14 PM GMT

✓ Eric Elliott (Eric.Elliott@bsci.com) authenticated with Adobe Acrobat Sign.

Challenge: The user opened the agreement.

2024-03-04 - 4:15:37 PM GMT

✓ Eric Elliott (Eric.Elliott@bsci.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

2024-03-04 - 4:16:08 PM GMT

✓ Eric Elliott (Eric.Elliott@bsci.com) has agreed to the terms of use and to do business electronically with Boston Scientific

2024-03-04 - 4:16:09 PM GMT

✓ Document e-signed by Eric Elliott (Eric.Elliott@bsci.com)

Signing reason: I am the Approver

Signature Date: 2024-03-04 - 4:16:09 PM GMT - Time Source: server

✓ Agreement completed.

2024-03-04 - 4:16:09 PM GMT