

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 2546 First Street, Propark El Coyol, Alajuela COSTA RICA
EU Authorized Representative: And SRN#	Boston Scientific Limited Ballybrit Business Park Galway IRELAND SRN: IE-AR-000003840
Product(s):	OptiCross™ Coronary Imaging Catheter OptiCross™ 6 Coronary Imaging Catheter OptiCross™ HD Coronary Imaging Catheter OptiCross™ 6 HD Coronary Imaging Catheter Tech Doc File: 92811492 BUDI-DI: 01915060000000000000328N5
Risk Classification:	The OptiCross, OptiCross 6, OptiCross HD, and OptiCross 6 HD Coronary Imaging Catheters are classified as Class III in conformity with Annex VIII, Chapter III, Rule 6 of Regulation 2017/745.

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:	The OptiCross Family Catheters are intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.
Date of Initial DoC Sign-Off under MDR	December 14, 2023

Model Designations			
Finished Goods Number (e.g., UPN)	Description	Guide Catheter Compatibility	Length
H749518100	OptiCross™ 40 MHz	5 F (≥ 0.058")	135 cm
H749518120	OptiCross™ 40 MHz	5 F (≥ 0.058")	135 cm
H749518140	OptiCross™ 40 MHz (bagless)	5 F (≥ 0.058")	135 cm
H7495181260	OptiCross™ 6 40 MHz	6 F (≥ 0.064")	135 cm
H7495181460	OptiCross™ 6 40 MHz (bagless)	6 F (≥ 0.064")	135 cm
H74939352020	OptiCross™ HD 60 MHz	5 F (≥ 0.058")	135 cm
H74939352030	OptiCross™ HD 60 MHz	5 F (≥ 0.058")	135 cm
H74939352060	OptiCross™ HD 60 MHz (bagless)	5 F (≥ 0.058")	135 cm
H74939354060	OptiCross™ 6 HD 60 MHz	6 F (≥ 0.064")	135 cm
H74939354070	OptiCross™ 6 HD 60 MHz	6 F (≥ 0.064")	135 cm

Model Designations			
Finished Goods Number (e.g., UPN)	Description	Guide Catheter Compatibility	Length
H74939354100	OptiCross™ 6 HD 60 MHz (bagless)	6 F (≥ 0.064")	135 cm

Certificates	
Certificate Name	Certificate Numbers
DEKRA EU Quality Management System Certification.	3830129CE01
DEKRA EU Technical Documentation Assessment.	3832142TD01
DEKRA Management System Certificate - EN ISO/ISO 13485:2016	3818536
Quality Management System - EN ISO/ISO 13485:2016 (Coyol)	MD 670368

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

* For Class I non-sterile non-measuring, certificate tables above can be removed.


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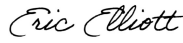
Additional EU Legislation Requiring Declarations of Conformity: Not Applicable.

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: Erin Farrens
Title: Senior Director, Quality Assurance
Signature:  Electronically signed by:
Erin Hyndman-Farrens
Reason: I am the Approver
Date: Sep 11, 2024 11:56
CDT
Date: USA

Name: Eric Elliott
Title: Director, Regulatory Affairs
Signature:  Electronically signed by:
Eric Elliott
Reason: I am the Approver
Date: Sep 11, 2024 09:03
CDT
Date: 11-Sep-2024
USA

Name: Andrew Bicek
Title: Director, Research and Development
Signature:  Electronically signed by:
Andrew Bicek
Reason: I am the Approver
Date: Sep 11, 2024 08:10
CDT
Date: 11-Sep-2024
USA

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









92811503 OptiCross Catheter Family DoC

Final Audit Report

2024-09-11

Created:	2024-09-11
By:	Cassandra Clark (Cassie.Clark@bsci.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA-ghSqCgxPkk78nk_IRb6P1CR-bNA6lr7
Number of Documents:	1
Document page count:	4
Number of supporting files:	0
Supporting files page count:	0

"92811503 OptiCross Catheter Family DoC" History

-  Document created by Cassandra Clark (Cassie.Clark@bsci.com)
2024-09-11 - 3:12:31 PM GMT
-  Document emailed to erin.farrens@bsci.com for signature
2024-09-11 - 3:13:15 PM GMT
-  Email viewed by erin.farrens@bsci.com
2024-09-11 - 4:31:48 PM GMT
-  Cassandra Clark (Cassie.Clark@bsci.com) replaced signer erin.farrens@bsci.com with Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com)
2024-09-11 - 4:34:59 PM GMT
-  Document emailed to Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com) for signature
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2024-09-11 - 4:36:06 PM GMT
-  Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
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-  Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com) authenticated with Adobe Acrobat Sign.
Challenge: The user opened the agreement.
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✔ Erin Hyndman-Farrens (erin.hyndman-farrens@bsci.com) authenticated with Adobe Acrobat Sign.

Challenge: The user completed the signing ceremony.

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

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

Signing reason: I am the Approver

Signature Date: 2024-09-11 - 4:56:36 PM GMT - Time Source: server

✔ Agreement completed.

2024-09-11 - 4:56:36 PM GMT