Digitally signed by Chicu Natalia
Date: 2024.12.09 10:31:52 EET
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Location: Moldova
MOLDOVA EUROPEANĂ

Number: 3832142TD01

EU Technical Documentation Assessment Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter II and III

Manufacturer:

Boston Scientific Corporation

300 Boston Scientific Way
Marlborough
MA 01752
USA
SRN ID.: US-MF-000004702

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 3812454CN

Authorized Representative: Boston Scientific Limited, Ballybrit Business Park, Galway, Ireland.

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **16 June 2023** Date: **8 April 2024** Expiry date**: 16 June 2028**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

Number: 3832142TD01

EU Technical Documentation Assessment Certificate

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This certificate covers the following device(s):

Class III	
Basic UDI-DI: 01915060000000000000328N5 **Device Name:** OptiCross Coronary Imaging Catheter **Model:** H749518100 **Model:** H749518120 **Device Name:** OptiCross 6 Coronary Imaging Catheter **Model:** H7495181260 **Device Name:** OptiCross HD Coronary Imaging Catheter **Model:** H74939352020 **Model:** H74939352030 **Device Name**: OptiCross 6 HD Coronary Imaging Catheter **Model:** H74939354060 **Model:** H74939354070 **Type:** Cardiac and Intracoronary Ultrasound Catheters (C0104010102)	*Intended Purpose:* The OptiCross coronary imaging family catheters are intended for ultrasound examination of coronary intravascular pathology only.

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Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	16 June 2023	3812454CN103	Initial
1	8 April 2024	3812454CN106	Revised

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