

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA
Manufacturing Site:	Boston Scientific Corporation. Two Scimed Place Maple Grove MN 55311 USA
EU Authorized Representative:	Boston Scientific Limited Ballybrit Business Park Galway IRELAND
Product:	Maverick™ XL MONORAIL™ PTCA Dilatation Catheter Design Dossier: 90344072 See Attachment A Model Designation Summary.
Classification:	Class III, Rule 6 according to Annex IX of the MDD.
Notified Body:	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem THE NETHERLANDS Identification Number: 0344
First CE Marking Under DEKRA:	01 March 2012

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EC Certificates	
Certificate Name	Certificate Numbers
DEKRA Full Quality Assurance System Certificate	3812454CE01
DEKRA EC Design-Examination Certificate	3812454DE20
DEKRA Management System Certificate - EN ISO 13485:2016	3818536

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: Brandon Erickson
Title: Director, Quality Assurance

Signature:  _____ 20 Aug 2018
Date

Name: Steve James
Title: Director, Regulatory Affairs
Interventional Cardiology

Signature:  _____ 16 Aug 2018
Date

ATTACHMENT A

Model Designation Summary

UPN	GTIN	Dimensions (balloon diameter x length)
H7493790940150	08714729390275	4.0 mm x 15 mm
H7493790945150	08714729390299	4.5 mm x 15 mm
H7493790950150	08714729390312	5.0 mm x 15 mm
H7493790955150	08714729390336	5.5 mm x 15 mm
H7493790960150	08714729390350	6.0 mm x 15 mm
H7493790940200	08714729390282	4.0 mm x 20 mm
H7493790945200	08714729390305	4.5 mm x 20 mm
H7493790950200	08714729390329	5.0 mm x 20 mm
H7493790955200	08714729390343	5.5 mm x 20 mm
H7493790960200	08714729390367	6.0 mm x 20 mm