

EC DECLARATION OF CONFORMITY

Legal Manufacturer:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

Manufacturing Site(s):

Boston Scientific Corporation.
Two Scimed Place
Maple Grove MN 55311
USA

Boston Scientific Medical Device
(Malaysia) SDN BHD
PMT 741, Persiaran Cassia Selatan 1,
Taman Perindustrian Batu Kawan,
14110 Bandar Cassia,
Pulau Pinang
Malaysia

EU Authorized Representative:

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

Product:

**Maverick2™ MONORAIL™ PTCA
Dilatation Catheter**

Design Dossier: 90164331
See Attachment A for Model Designations.

Classification:

Class III, Rule 6 according to Annex IX of
the MDD.

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MANUFACTURE OR SALE OF APPARATUS WITHOUT THE EXPRESS WRITTEN CONSENT OF BOSTON SCIENTIFIC CORP.

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

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 (Maple Grove)	3818536
BSI Management System Certificate – EN ISO 13485:2016 (Pulau Pinang)	MD 670368

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:

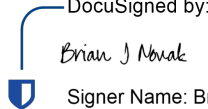
Name: Brandon Erickson
Title: Director, Quality Assurance

Signature: 
DocuSigned by:
Brandon Erickson
Signer Name: Brandon Erickson
Signing Reason: I approve this document
Signing Time: 09 September 2020 | 3:14:41 PM EDT
67F0691FA4F14723A4D0A4481A68EB7C

09 September 2020

Date

Name: Brian J Novak
Title: VP, Regulatory Affairs
Interventional Cardiology

Signature: 
DocuSigned by:
Brian J Novak
Signer Name: Brian J Novak
Signing Reason: I approve this document
Signing Time: 09 September 2020 | 12:00:09 PM PDT
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09 September 2020

Date

ATTACHMENT A

Model Designation Summary

UPN	GTIN	Dimensions
H7493892809200	08714729369875	2.0 mm x 9mm
H7493892809220	08714729369882	2.25 mm x 9 mm
H7493892809250	08714729369899	2.5 mm x 9 mm
H7493892809270	08714729369905	2.75 mm x 9 mm
H7493892809300	08714729369912	3.0 mm x 9 mm
H7493892809320	08714729369929	3.25 mm x 9 mm
H7493892809350	08714729369936	3.5 mm x 9 mm
H7493892809370	08714729369943	3.75 mm x 9 mm
H7493892809400	08714729369950	4.0 mm x 9 mm
H7493892812200	08714729369967	2.0 mm x 12 mm
H7493892812220	08714729369974	2.25 mm x 12 mm
H7493892812250	08714729369981	2.5 mm x 12 mm
H7493892812270	08714729369998	2.75 mm x 12 mm
H7493892812300	08714729370000	3.0 mm x 12 mm
H7493892812320	08714729370017	3.25 mm x 12 mm
H7493892812350	08714729370024	3.5 mm x 12 mm
H7493892812370	08714729370031	3.75 mm x 12 mm
H7493892812400	08714729370048	4.0 mm x 12 mm
H7493892815150	08714729370055	1.5 mm x 15 mm
H7493892815200	08714729370062	2.0 mm x 15 mm
H7493892815220	08714729370079	2.25 mm x 15 mm
H7493892815250	08714729370086	2.5 mm x 15 mm
H7493892815270	08714729370093	2.75 mm x 15 mm
H7493892815300	08714729370109	3.0 mm x 15 mm
H7493892815320	08714729370116	3.25 mm x 15 mm
H7493892815350	08714729370123	3.5 mm x 15 mm

UPN	GTIN	Dimensions
H7493892815370	08714729370130	3.75 mm x 15 mm
H7493892815400	08714729370147	4.0 mm x 15 mm
H7493892820150	08714729370154	1.5 mm x 20 mm
H7493892820200	08714729370161	2.0 mm x 20 mm
H7493892820220	08714729370178	2.25 mm x 20 mm
H7493892820250	08714729370185	2.5 mm x 20 mm
H7493892820270	08714729370192	2.75 mm x 20 mm
H7493892820300	08714729370208	3.0 mm x 20 mm
H7493892820320	08714729370215	3.25 mm x 20 mm
H7493892820350	08714729370222	3.5 mm x 20 mm
H7493892820370	08714729370239	3.75 mm x 20 mm
H7493892820400	08714729370246	4.0 mm x 20 mm
H7493892825200	08714729370253	2.0 mm x 25 mm
H7493892825220	08714729370260	2.25 mm x 25 mm
H7493892825250	08714729370277	2.5 mm x 25 mm
H7493892825270	08714729370284	2.75 mm x 25 mm
H7493892825300	08714729370291	3.0 mm x 25 mm
H7493892825320	08714729370307	3.25 mm x 25 mm
H7493892825350	08714729370314	3.5 mm x 25 mm
H7493892825370	08714729370321	3.75 mm x 25 mm
H7493892825400	08714729370338	4.0 mm x 25 mm
H7493892830200	08714729370345	2.0 mm x 30 mm
H7493892830220	08714729370352	2.25 mm x 30 mm
H7493892830250	08714729370369	2.5 mm x 30 mm
H7493892830270	08714729370376	2.75 mm x 30 mm
H7493892830300	08714729370383	3.0 mm x 30 mm
H7493892830320	08714729370390	3.25 mm x 30 mm
H7493892830350	08714729370406	3.5 mm x 30 mm
H7493892830370	08714729370413	3.75 mm x 30 mm
H7493892830400	08714729370420	4.0 mm x 30 mm

UPN	GTIN	Dimensions
N / A	N / A	1.5 mm x 9 mm
N / A	N / A	1.5 mm x 12 mm
N / A	N / A	1.5 mm x 25 mm
N / A	N / A	1.5 mm x 30 mm