

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

European Representative: Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

Products: •Apex™ MONORAIL™ PTCA Dilatation Catheter
•Apex™ Flex MONORAIL™ PTCA Dilatation Catheter
•Apex™ Push MONORAIL™ PTCA Dilatation Catheter
•Apex™ OVER-THE-WIRE PTCA Dilatation Catheter
•Apex™ Flex Over-The-Wire PTCA Dilatation Catheter
•Apex™ Push OVER-THE-WIRE PTCA Dilatation Catheter
Design Dossier: 90362300
See Attachment A for Model Designations.

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

Date of CE Marking Under DEKRA: 31 January 2012

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EC Certificates	
Certificate Name	Certificate Numbers
DEKRA Full Quality Assurance System Certificate	3812454CE01
DEKRA EC Design-Examination Certificate	3812454DE17
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

Apex Push MONORAIL PTCA Dilatation Catheter

UPN	GTIN	Dimension
H7493896108150	08714729475996	1.5 mm x 8 mm
H7493896112150	08714729758457	1.5 mm x 12 mm
H7493896115150	08714729476009	1.5 mm x 15 mm
H7493896120150	08714729476016	1.5 mm x 20 mm

Apex Flex MONORAIL PTCA Dilatation Catheter

UPN	GTIN	Dimension
H7493895908150	08714729475354	1.5 mm x 8 mm
H7493895912150	08714729758464	1.5 mm x 12 mm
H7493895915150	08714729475583	1.5 mm x 15 mm
H7493895920150	08714729475705	1.5 mm x 20 mm

Apex MONORAIL PTCA Dilatation Catheter

UPN	GTIN	Dimension
H7493895908200	08714729475361	2.0 mm x 8 mm
H7493895908220	08714729475378	2.25 mm x 8mm
H7493895908250	08714729475385	2.5 mm x 8 mm
H7493895908270	08714729475392	2.75 mm x 8 mm
H7493895908300	08714729475408	3.0 mm x 8 mm
H7493895908320	08714729475415	3.25 mm x 8 mm
H7493895908350	08714729475422	3.5 mm x 8 mm
H7493895908370	08714729475439	3.75 mm x 8 mm
H7493895908400	08714729475446	4.0 mm x 8 mm
H7493895908450	08714729475453	4.25 mm x 8 mm
H7493895908500	08714729475460	5.0 mm x 8 mm
H7493895912200	08714729475484	2.0 mm x 12 mm
H7493895912220	08714729475491	2.25 mm x 12 mm
H7493895912250	08714729475507	2.5 mm x 12 mm
H7493895912270	08714729475514	2.75 mm x 12 mm
H7493895912300	08714729475521	3.0 mm x 12 mm
H7493895912320	08714729475538	3.25 mm x 12 mm
H7493895912350	08714729475545	3.5 mm x 12 mm

Apex MONORAIL PTCA Dilatation Catheter

UPN	GTIN	Dimension
H7493895912370	08714729475552	3.75 mm x 12 mm
H7493895912400	08714729475569	4.0 mm x 12 mm
H7493895912450	08714729475576	4.5 mm x 12 mm
H7493895912500	08714729475484	5.0 mm x 12 mm
H7493895915200	08714729475590	2.0 mm x 15 mm
H7493895915220	08714729475606	2.25 mm x 15 mm
H7493895915250	08714729475613	2.5 mm x 15 mm
H7493895915270	08714729475620	2.75 mm x 15 mm
H7493895915300	08714729475637	3.0 mm x 15 mm
H7493895915320	08714729475644	3.25 mm x 15 mm
H7493895915350	08714729475651	3.5 mm x 15 mm
H7493895915370	08714729475668	3.75 mm x 15 mm
H7493895915400	08714729475675	4.0 mm x 15 mm
H7493895915450	08714729475682	4.5 mm x 15 mm
H7493895915500	08714729475699	5.0 mm x 15 mm
H7493895920200	08714729475712	2.0 mm x 20 mm
H7493895920220	08714729475729	2.25 mm x 20 mm
H7493895920250	08714729475736	2.5 mm x 20 mm
H7493895920270	08714729475743	2.75 mm x 20 mm
H7493895920300	08714729475750	3.0 mm x 20 mm
H7493895920320	08714729475767	3.25 mm x 20 mm
H7493895920350	08714729475774	3.5 mm x 20 mm
H7493895920370	08714729475781	3.75 mm x 20 mm
H7493895920400	08714729475798	4.0 mm x 20 mm
H7493895920450	08714729475804	4.5 mm x 20 mm
H7493895920500	08714729475811	5.0 mm x 20 mm
H7493895930200	08714729475828	2.0 mm x 30 mm
H7493895930220	08714729475835	2.25 mm x 30 mm
H7493895930250	08714729475842	2.5 mm x 30 mm
H7493895930270	08714729475859	2.75 mm x 30 mm
H7493895930300	08714729475866	3.0 mm x 30 mm
H7493895930320	08714729475873	3.25 mm x 30 mm
H7493895930350	08714729475880	3.5 mm x 30 mm
H7493895930370	08714729475897	3.75 mm x 30 mm
H7493895930400	08714729475903	4.0 mm x 30 mm
H7493895940200	08714729475910	2.0 mm x 40 mm
H7493895940250	08714729475927	2.5 mm x 40 mm
H7493895940300	08714729475934	3.0 mm x 40 mm
H7493895940350	08714729475941	3.5 mm x 40 mm
H7493895940400	08714729475958	4.0 mm x 40 mm

Apex Push Over-The-Wire PTCA Dilatation Catheter

UPN	GTIN	Dimensions
H7493896008150	08714729475965	1.5 mm x 8 mm
H7493896012150	08714729758631	1.5 mm x 12 mm
H7493896015150	08714729475972	1.5 mm x 15 mm
H7493896020150	08714729475989	1.5 mm x 20 mm

Apex Flex Over-The-Wire PTCA Dilatation Catheter

UPN	GTIN	Dimensions
H7493895808150	08714729474746	1.5 mm x 8 mm
H7493895812150	08714729760597	1.5 mm x 12 mm
H7493895815150	08714729474975	1.5 mm x 15 mm
H7493895820150	08714729475095	1.5 mm x 20 mm

Apex Over-The-Wire PTCA Dilatation Catheter

UPN	GTIN	Dimensions
H7493895808200	08714729474753	2.0 mm x 8 mm
H7493895808220	08714729474760	2.25 mm x 8mm
H7493895808250	08714729474777	2.5 mm x 8 mm
H7493895808270	08714729474784	2.75 mm x 8 mm
H7493895808300	08714729474791	3.0 mm x 8 mm
H7493895808320	08714729474807	3.25 mm x 8 mm
H7493895808350	08714729474814	3.5 mm x 8 mm
H7493895808370	08714729474821	3.75 mm x 8 mm
H7493895808400	08714729474838	4.0 mm x 8 mm
H7493895808450	08714729474845	4.25 mm x 8 mm
H7493895808500	08714729474852	5.0 mm x 8 mm
H7493895812200	08714729474869	2.0 mm x 12 mm
H7493895812220	08714729474876	2.25 mm x 12 mm
H7493895812250	08714729474883	2.5 mm x 12 mm
H7493895812270	08714729474890	2.75 mm x 12 mm
H7493895812300	08714729474906	3.0 mm x 12 mm
H7493895812320	08714729474913	3.25 mm x 12 mm
H7493895812350	08714729474920	3.5 mm x 12 mm
H7493895812370	08714729474937	3.75 mm x 12 mm
H7493895812400	08714729474944	4.0 mm x 12 mm
H7493895812450	08714729474951	4.5 mm x 12 mm
H7493895812500	08714729474968	5.0 mm x 12 mm

Apex Over-The-Wire PTCA Dilatation Catheter

UPN	GTIN	Dimensions
H7493895815200	08714729474982	2.0 mm x 15 mm
H7493895815220	08714729474999	2.25 mm x 15 mm
H7493895815250	08714729475002	2.5 mm x 15 mm
H7493895815270	08714729475019	2.75 mm x 15 mm
H7493895815300	08714729475026	3.0 mm x 15 mm
H7493895815320	08714729475033	3.25 mm x 15 mm
H7493895815350	08714729475040	3.5 mm x 15 mm
H7493895815370	08714729475057	3.75 mm x 15 mm
H7493895815400	08714729475064	4.0 mm x 15 mm
H7493895815450	08714729475071	4.5 mm x 15 mm
H7493895815500	08714729475088	5.0 mm x 15 mm
H7493895820200	08714729475101	2.0 mm x 20 mm
H7493895820220	08714729475118	2.25 mm x 20 mm
H7493895820250	08714729475125	2.5 mm x 20 mm
H7493895820270	08714729475132	2.75 mm x 20 mm
H7493895820300	08714729475149	3.0 mm x 20 mm
H7493895820320	08714729475156	3.25 mm x 20 mm
H7493895820350	08714729475163	3.5 mm x 20 mm
H7493895820370	08714729475170	3.75 mm x 20 mm
H7493895820400	08714729475187	4.0 mm x 20 mm
H7493895820450	08714729475194	4.5 mm x 20 mm
H7493895820500	08714729475200	5.0 mm x 20 mm
H7493895830200	08714729475217	2.0 mm x 30 mm
H7493895830220	08714729475224	2.25 mm x 30 mm
H7493895830250	08714729475231	2.5 mm x 30 mm
H7493895830270	08714729475248	2.75 mm x 30 mm
H7493895830300	08714729475255	3.0 mm x 30 mm
H7493895830320	08714729475262	3.25 mm x 30 mm
H7493895830350	08714729475279	3.5 mm x 30 mm
H7493895830370	08714729475286	3.75 mm x 30 mm
H7493895830400	08714729475293	4.0 mm x 30 mm
H7493895840200	08714729475309	2.0 mm x 40 mm
H7493895840250	08714729475316	2.5 mm x 40 mm
H7493895840300	08714729475323	3.0 mm x 40 mm
H7493895840350	08714729475330	3.5 mm x 40 mm
H7493895840400	08714729475347	4.0 mm x 40 mm