

DECLARATION OF CONFORMITY

Legal Manufacturer:

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
USA

Manufacturing Site(s):

Boston Scientific Ireland Ltd.
Ballybrit Business Park
Galway
Ireland

Boston Scientific Plymouth MN
5905 Nathan Lane
Plymouth, MN 55442, USA

European Representative:

Boston Scientific International S.A.
55 avenue des Champs Pierreux
TSA 51101
92729 NANTERRE CEDEX
FRANCE

Products:

PROMUS Element™ Plus MONORAIL™ BTK
Everolimus-Eluting Stent System
PROMUS Element™ Plus OVER-THE-WIRE BTK
Everolimus-Eluting Stent System
(Design Dossier GAL-DD-90453488). A listing of UPNs is
included in Attachment 1 of this document.

Classification:

Class III device in conformity with Annex IX, Rules 8 & 13
in the Medical Device Directive 93/42/EEC.

Notified Body:

DEKRA Certification B.V.
Utrechtseweg 310, 6812 AR Arnhem
P.O. Box 5185, 6802 ED Arnhem
The Netherlands

EC Notified Body Number:

0344

EC Certificates	
Certificate Name	Certificate Number
Annex II.3	3807055CE01
Annex II.4	3807055DE29
EN ISO 13485:2012 + AC:2012	3307055

We declare that the product identified above is in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal Manufacturer.

Date of first CE Marking: Refer to Attachment 1

Signatures, Date of Issue:

Name: John Donohue
Title: Vice President, Quality Assurance
Cardiovascular Business

Signature: John Donohue **Date:** 30 MAY 2013

Name: Robbie Walsh
Title: Director, Regulatory Affairs
Interventional Cardiology

Signature: Robbie Walsh **Date:** 6 June 2013

ATTACHMENT 1

PROMUS Element™ Plus MONORAIL™ BTK Everolimus -Eluting Stent System Universal Part Numbers are listed below.

CE Mark Date: 12 April 2012

Product Name / Size (Length x diameter)	Model	UPN
PROMUS Element™ Plus MONORAIL™ BTK / 8 mm x 2.25 mm	Small Vessel	H74939215220810
PROMUS Element™ Plus MONORAIL™ BTK / 12 mm x 2.25 mm	Small Vessel	H74939215221210
PROMUS Element™ Plus MONORAIL™ BTK / 16 mm x 2.25 mm	Small Vessel	H74939215221610
PROMUS Element™ Plus MONORAIL™ BTK / 20 mm x 2.25 mm	Small Vessel	H74939215222010
PROMUS Element™ Plus MONORAIL™ BTK / 24 mm x 2.25 mm	Small Vessel	H74939215222410
PROMUS Element™ Plus MONORAIL™ BTK / 28 mm x 2.25 mm	Small Vessel	H74939215222810
PROMUS Element™ Plus MONORAIL™ BTK / 32 mm x 2.25 mm	Small Vessel	H74939215223210
PROMUS Element™ Plus MONORAIL™ BTK / 8 mm x 2.50 mm	Small Work Horse	H74939215250810
PROMUS Element™ Plus MONORAIL™ BTK / 12 mm x 2.50 mm	Small Work Horse	H74939215251210
PROMUS Element™ Plus MONORAIL™ BTK / 16 mm x 2.50 mm	Small Work Horse	H74939215251610
PROMUS Element™ Plus MONORAIL™ BTK / 20 mm x 2.50 mm	Small Work Horse	H74939215252010
PROMUS Element™ Plus MONORAIL™ BTK / 24 mm x 2.50 mm	Small Work Horse	H74939215252410
PROMUS Element™ Plus MONORAIL™ BTK / 28 mm x 2.50 mm	Small Work Horse	H74939215252810
PROMUS Element™ Plus MONORAIL™ BTK / 32 mm x 2.50 mm	Small Work Horse	H74939215253210
PROMUS Element™ Plus MONORAIL™ BTK / 38 mm x 2.50 mm	Small Work Horse	H74939215253810
PROMUS Element™ Plus MONORAIL™ BTK / 8 mm x 2.75 mm	Small Work Horse	H74939215270810
PROMUS Element™ Plus MONORAIL™ BTK / 12 mm x 2.75 mm	Small Work Horse	H74939215271210
PROMUS Element™ Plus MONORAIL™ BTK / 16 mm x 2.75 mm	Small Work Horse	H74939215271610
PROMUS Element™ Plus MONORAIL™ BTK / 20 mm x 2.75 mm	Small Work Horse	H74939215272010
PROMUS Element™ Plus MONORAIL™ BTK / 24 mm x 2.75 mm	Small Work Horse	H74939215272410
PROMUS Element™ Plus MONORAIL™ BTK / 28 mm x 2.75 mm	Small Work Horse	H74939215272810
PROMUS Element™ Plus MONORAIL™ BTK / 32 mm x 2.75 mm	Small Work Horse	H74939215273210
PROMUS Element™ Plus MONORAIL™ BTK / 38 mm x 2.75 mm	Small Work Horse	H74939215273810
PROMUS Element™ Plus MONORAIL™ BTK / 8 mm x 3.00 mm	Work Horse	H74939215300810
PROMUS Element™ Plus MONORAIL™ BTK / 12 mm x 3.00 mm	Work Horse	H74939215301210
PROMUS Element™ Plus MONORAIL™ BTK / 16 mm x 3.00 mm	Work Horse	H74939215301610
PROMUS Element™ Plus MONORAIL™ BTK / 20 mm x 3.00 mm	Work Horse	H74939215302010
PROMUS Element™ Plus MONORAIL™ BTK / 24 mm x 3.00 mm	Work Horse	H74939215302410

Product Name / Size (Length x diameter)	Model	UPN
PROMUS Element™ Plus MONORAIL™ BTK / 28 mm x 3.00 mm	Work Horse	H74939215302810
PROMUS Element™ Plus MONORAIL™ BTK / 32 mm x 3.00 mm	Work Horse	H74939215303210
PROMUS Element™ Plus MONORAIL™ BTK / 38 mm x 3.00 mm	Work Horse	H74939215303810
PROMUS Element™ Plus MONORAIL™ BTK / 8 mm x 3.50 mm	Work Horse	H74939215350810
PROMUS Element™ Plus MONORAIL™ BTK / 12 mm x 3.50 mm	Work Horse	H74939215351210
PROMUS Element™ Plus MONORAIL™ BTK / 16 mm x 3.50 mm	Work Horse	H74939215351610
PROMUS Element™ Plus MONORAIL™ BTK / 20 mm x 3.50 mm	Work Horse	H74939215352010
PROMUS Element™ Plus MONORAIL™ BTK / 24 mm x 3.50 mm	Work Horse	H74939215352410
PROMUS Element™ Plus MONORAIL™ BTK / 28 mm x 3.50 mm	Work Horse	H74939215352810
PROMUS Element™ Plus MONORAIL™ BTK / 32 mm x 3.50 mm	Work Horse	H74939215353210
PROMUS Element™ Plus MONORAIL™ BTK / 38 mm x 3.50 mm	Work Horse	H74939215353810
PROMUS Element™ Plus MONORAIL™ BTK / 8 mm x 4.00 mm	Large Vessel	H74939215400810
PROMUS Element™ Plus MONORAIL™ BTK / 12 mm x 4.00 mm	Large Vessel	H74939215401210
PROMUS Element™ Plus MONORAIL™ BTK / 16 mm x 4.00 mm	Large Vessel	H74939215401610
PROMUS Element™ Plus MONORAIL™ BTK / 20 mm x 4.00 mm	Large Vessel	H74939215402010
PROMUS Element™ Plus MONORAIL™ BTK / 24 mm x 4.00 mm	Large Vessel	H74939215402410
PROMUS Element™ Plus MONORAIL™ BTK / 28 mm x 4.00 mm	Large Vessel	H74939215402810
PROMUS Element™ Plus MONORAIL™ BTK / 32 mm x 4.00 mm	Large Vessel	H74939215403210
PROMUS Element™ Plus MONORAIL™ BTK / 38 mm x 4.00 mm	Large Vessel	H74939215403810

**PROMUS Element™ Plus OVER-THE-WIRE BTK Everolimus -Eluting Stent System
Universal Part Numbers are listed below.**

CE Mark Date: 22 June 2012

Product Name / Size (Length x diameter)	Model	UPN
PROMUS Element™ Plus OVER-THE-WIRE BTK / 8 mm x 2.25 mm	Small Vessel	H74939227220810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 12 mm x 2.25 mm	Small Vessel	H74939227221210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 16 mm x 2.25 mm	Small Vessel	H74939227221610
PROMUS Element™ Plus OVER-THE-WIRE BTK / 20 mm x 2.25 mm	Small Vessel	H74939227222010
PROMUS Element™ Plus OVER-THE-WIRE BTK / 24 mm x 2.25 mm	Small Vessel	H74939227222410
PROMUS Element™ Plus OVER-THE-WIRE BTK / 28 mm x 2.25 mm	Small Vessel	H74939227222810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 32 mm x 2.25 mm	Small Vessel	H74939227223210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 8 mm x 2.50 mm	Small Work Horse	H74939227250810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 12 mm x 2.50 mm	Small Work Horse	H74939227251210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 16 mm x 2.50 mm	Small Work Horse	H74939227251610
PROMUS Element™ Plus OVER-THE-WIRE BTK / 20 mm x 2.50 mm	Small Work Horse	H74939227252010
PROMUS Element™ Plus OVER-THE-WIRE BTK / 24 mm x 2.50 mm	Small Work Horse	H74939227252410
PROMUS Element™ Plus OVER-THE-WIRE BTK / 28 mm x 2.50 mm	Small Work Horse	H74939227252810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 32 mm x 2.50 mm	Small Work Horse	H74939227253210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 38 mm x 2.50 mm	Small Work Horse	H74939227253810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 8 mm x 2.75 mm	Small Work Horse	H74939227270810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 12 mm x 2.75 mm	Small Work Horse	H74939227271210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 16 mm x 2.75 mm	Small Work Horse	H74939227271610
PROMUS Element™ Plus OVER-THE-WIRE BTK / 20 mm x 2.75 mm	Small Work Horse	H74939227272010
PROMUS Element™ Plus OVER-THE-WIRE BTK / 24 mm x 2.75 mm	Small Work Horse	H74939227272410
PROMUS Element™ Plus OVER-THE-WIRE BTK / 28 mm x 2.75 mm	Small Work Horse	H74939227272810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 32 mm x 2.75 mm	Small Work Horse	H74939227273210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 38 mm x 2.75 mm	Small Work Horse	H74939227273810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 8 mm x 3.00 mm	Work Horse	H74939227300810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 12 mm x 3.00 mm	Work Horse	H74939227301210

Product Name / Size (Length x diameter)	Model	UPN
PROMUS Element™ Plus OVER-THE-WIRE BTK / 16 mm x 3.00 mm	Work Horse	H74939227301610
PROMUS Element™ Plus OVER-THE-WIRE BTK / 20 mm x 3.00 mm	Work Horse	H74939227302010
PROMUS Element™ Plus OVER-THE-WIRE BTK / 24 mm x 3.00 mm	Work Horse	H74939227302410
PROMUS Element™ Plus OVER-THE-WIRE BTK / 28 mm x 3.00 mm	Work Horse	H74939227302810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 32 mm x 3.00 mm	Work Horse	H74939227303210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 38 mm x 3.00 mm	Work Horse	H74939227303810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 8 mm x 3.50 mm	Work Horse	H74939227350810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 12 mm x 3.50 mm	Work Horse	H74939227351210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 16 mm x 3.50 mm	Work Horse	H74939227351610
PROMUS Element™ Plus OVER-THE-WIRE BTK / 20 mm x 3.50 mm	Work Horse	H74939227352010
PROMUS Element™ Plus OVER-THE-WIRE BTK / 24 mm x 3.50 mm	Work Horse	H74939227352410
PROMUS Element™ Plus OVER-THE-WIRE BTK / 28 mm x 3.50 mm	Work Horse	H74939227352810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 32 mm x 3.50 mm	Work Horse	H74939227353210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 38 mm x 3.50 mm	Work Horse	H74939227353810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 8 mm x 4.00 mm	Large Vessel	H74939227400810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 12 mm x 4.00 mm	Large Vessel	H74939227401210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 16 mm x 4.00 mm	Large Vessel	H74939227401610
PROMUS Element™ Plus OVER-THE-WIRE BTK / 20 mm x 4.00 mm	Large Vessel	H74939227402010
PROMUS Element™ Plus OVER-THE-WIRE BTK / 24 mm x 4.00 mm	Large Vessel	H74939227402410
PROMUS Element™ Plus OVER-THE-WIRE BTK / 28 mm x 4.00 mm	Large Vessel	H74939227402810
PROMUS Element™ Plus OVER-THE-WIRE BTK / 32 mm x 4.00 mm	Large Vessel	H74939227403210
PROMUS Element™ Plus OVER-THE-WIRE BTK / 38 mm x 4.00 mm	Large Vessel	H74939227403810