

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 Corporation Two Scimed Place Maple Grove, MN 55311 USA 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™ MONORAIL™ Everolimus- Eluting Coronary Stent System PROMUS Element™ Plus MONORAIL™ Everolimus-Eluting Coronary 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	3807055DE13
EN ISO 13485:2012 + AC: 2012	3307055

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. 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 I

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™ MONORAIL™ Everolimus-Eluting Coronary Stent System Universal Part Numbers are listed below.

These following codes were CE Marked on 30 October 2009.

Product Name / Size (Length x diameter)	Model	UPN
PROMUS Element™ MONORAIL™ / 8 mm x 2.25 mm	Small Vessel	H7493911308220
PROMUS Element™ MONORAIL™ / 12 mm x 2.25 mm	Small Vessel	H7493911312220
PROMUS Element™ MONORAIL™ / 16 mm x 2.25 mm	Small Vessel	H7493911316220
PROMUS Element™ MONORAIL™ / 20 mm x 2.25 mm	Small Vessel	H7493911320220
PROMUS Element™ MONORAIL™ / 24 mm x 2.25 mm	Small Vessel	H7493911324220
PROMUS Element™ MONORAIL™ / 28 mm x 2.25 mm	Small Vessel	H7493911328220
PROMUS Element™ MONORAIL™ / 32 mm x 2.25 mm	Small Vessel	H7493911332220
PROMUS Element™ MONORAIL™ / 8 mm x 2.50 mm	Small Work Horse	H7493911308250
PROMUS Element™ MONORAIL™ / 12 mm x 2.50 mm	Small Work Horse	H7493911312250
PROMUS Element™ MONORAIL™ / 16 mm x 2.50 mm	Small Work Horse	H7493911316250
PROMUS Element™ MONORAIL™ / 20 mm x 2.50 mm	Small Work Horse	H7493911320250
PROMUS Element™ MONORAIL™ / 24 mm x 2.50 mm	Small Work Horse	H7493911324250
PROMUS Element™ MONORAIL™ / 28 mm x 2.50 mm	Small Work Horse	H7493911328250
PROMUS Element™ MONORAIL™ / 32 mm x 2.50 mm	Small Work Horse	H7493911332250
PROMUS Element™ MONORAIL™ / 8 mm x 2.75 mm	Small Work Horse	H7493911308270
PROMUS Element™ MONORAIL™ / 12 mm x 2.75 mm	Small Work Horse	H7493911312270
PROMUS Element™ MONORAIL™ / 16 mm x 2.75 mm	Small Work Horse	H7493911316270
PROMUS Element™ MONORAIL™ / 20 mm x 2.75 mm	Small Work Horse	H7493911320270
PROMUS Element™ MONORAIL™ / 24 mm x 2.75 mm	Small Work Horse	H7493911324270
PROMUS Element™ MONORAIL™ / 28 mm x 2.75 mm	Small Work Horse	H7493911328270
PROMUS Element™ MONORAIL™ / 32 mm x 2.75 mm	Small Work Horse	H7493911332270
PROMUS Element™ MONORAIL™ / 8 mm x 3.00 mm	Work Horse	H7493911308300
PROMUS Element™ MONORAIL™ / 12 mm x 3.00 mm	Work Horse	H7493911312300
PROMUS Element™ MONORAIL™ / 16 mm x 3.00 mm	Work Horse	H7493911316300
PROMUS Element™ MONORAIL™ / 20 mm x 3.00 mm	Work Horse	H7493911320300
PROMUS Element™ MONORAIL™ / 24 mm x 3.00 mm	Work Horse	H7493911324300
PROMUS Element™ MONORAIL™ / 28 mm x 3.00 mm	Work Horse	H7493911328300
PROMUS Element™ MONORAIL™ / 32 mm x 3.00 mm	Work Horse	H7493911332300
PROMUS Element™ MONORAIL™ / 8 mm x 3.50 mm	Work Horse	H7493911308350
PROMUS Element™ MONORAIL™ / 12 mm x 3.50 mm	Work Horse	H7493911312350
PROMUS Element™ MONORAIL™ / 16 mm x 3.50 mm	Work Horse	H7493911316350
PROMUS Element™ MONORAIL™ / 20 mm x 3.50 mm	Work Horse	H7493911320350
PROMUS Element™ MONORAIL™ / 24 mm x 3.50 mm	Work Horse	H7493911324350
PROMUS Element™ MONORAIL™ / 28 mm x 3.50 mm	Work Horse	H7493911328350

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PROMUS Element™ MONORAIL™ and PROMUS Element™ Plus MONORAIL™

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Product Name / Size (Length x diameter)	Model	UPN
PROMUS Element™ MONORAIL™ / 32 mm x 3.50 mm	Work Horse	H7493911332350
PROMUS Element™ MONORAIL™ / 8 mm x 4.00 mm	Large Vessel	H7493911308400
PROMUS Element™ MONORAIL™ / 12 mm x 4.00 mm	Large Vessel	H7493911312400
PROMUS Element™ MONORAIL™ / 16 mm x 4.00 mm	Large Vessel	H7493911316400
PROMUS Element™ MONORAIL™ / 20 mm x 4.00 mm	Large Vessel	H7493911320400
PROMUS Element™ MONORAIL™ / 24 mm x 4.00 mm	Large Vessel	H7493911324400
PROMUS Element™ MONORAIL™ / 28 mm x 4.00 mm	Large Vessel	H7493911328400
PROMUS Element™ MONORAIL™ / 32 mm x 4.00 mm	Large Vessel	H7493911332400

The following codes were CE Marked on 19 February 2010.

Product Name / Size (Length x diameter)	Model	UPN
PROMUS Element™ Long MONORAIL™/ 38 mm x 2.50 mm	Small Work Horse	H7493911338250
PROMUS Element™ Long MONORAIL™/ 38 mm x 2.75 mm	Small Work Horse	H7493911338270
PROMUS Element™ Long MONORAIL™/ 38 mm x 3.00 mm	Work Horse	H7493911338300
PROMUS Element™ Long MONORAIL™/ 38 mm x 3.50 mm	Work Horse	H7493911338350
PROMUS Element™ Long MONORAIL™/ 38 mm x 4.00 mm	Large Vessel	H7493911338400

PROMUS Element™ Plus MONORAIL™ Universal Part Numbers are listed below:
CE Mark Date: 13 June 2011

Product Name / Size (Length x diameter)	Model	UPN
PROMUS Element™ Plus MONORAIL™ / 8 mm x 2.25 mm	Small Vessel	H7493918408220
PROMUS Element™ Plus MONORAIL™ / 12 mm x 2.25 mm	Small Vessel	H7493918412220
PROMUS Element™ Plus MONORAIL™ / 16 mm x 2.25 mm	Small Vessel	H7493918416220
PROMUS Element™ Plus MONORAIL™ / 20 mm x 2.25 mm	Small Vessel	H7493918420220
PROMUS Element™ Plus MONORAIL™ / 24 mm x 2.25 mm	Small Vessel	H7493918424220
PROMUS Element™ Plus MONORAIL™ / 28 mm x 2.25 mm	Small Vessel	H7493918428220
PROMUS Element™ Plus MONORAIL™ / 32 mm x 2.25 mm	Small Vessel	H7493918432220
PROMUS Element™ Plus MONORAIL™ / 8 mm x 2.50 mm	Small Work Horse	H7493918408250
PROMUS Element™ Plus MONORAIL™ / 12 mm x 2.50 mm	Small Work Horse	H7493918412250
PROMUS Element™ Plus MONORAIL™ / 16 mm x 2.50 mm	Small Work Horse	H7493918416250
PROMUS Element™ Plus MONORAIL™ / 20 mm x 2.50 mm	Small Work Horse	H7493918420250
PROMUS Element™ Plus MONORAIL™ / 24 mm x 2.50 mm	Small Work Horse	H7493918424250
PROMUS Element™ Plus MONORAIL™ / 28 mm x 2.50 mm	Small Work Horse	H7493918428250
PROMUS Element™ Plus MONORAIL™ / 32 mm x 2.50 mm	Small Work Horse	H7493918432250
PROMUS Element™ Plus MONORAIL™ / 38 mm x 2.50 mm	Small Work Horse	H7493918438250
PROMUS Element™ Plus MONORAIL™ / 8 mm x 2.75 mm	Small Work Horse	H7493918408270
PROMUS Element™ Plus MONORAIL™ / 12 mm x 2.75 mm	Small Work Horse	H7493918412270
PROMUS Element™ Plus MONORAIL™ / 16 mm x 2.75 mm	Small Work Horse	H7493918416270
PROMUS Element™ Plus MONORAIL™ / 20 mm x 2.75 mm	Small Work Horse	H7493918420270
PROMUS Element™ Plus MONORAIL™ / 24 mm x 2.75 mm	Small Work Horse	H7493918424270
PROMUS Element™ Plus MONORAIL™ / 28 mm x 2.75 mm	Small Work Horse	H7493918428270
PROMUS Element™ Plus MONORAIL™ / 32 mm x 2.75 mm	Small Work Horse	H7493918432270
PROMUS Element™ Plus MONORAIL™ / 38 mm x 2.75 mm	Small Work Horse	H7493918438270
PROMUS Element™ Plus MONORAIL™ / 8 mm x 3.00 mm	Work Horse	H7493918408300
PROMUS Element™ Plus MONORAIL™ / 12 mm x 3.00 mm	Work Horse	H7493918412300
PROMUS Element™ Plus MONORAIL™ / 16 mm x 3.00 mm	Work Horse	H7493918416300
PROMUS Element™ Plus MONORAIL™ / 20 mm x 3.00 mm	Work Horse	H7493918420300
PROMUS Element™ Plus MONORAIL™ / 24 mm x 3.00 mm	Work Horse	H7493918424300
PROMUS Element™ Plus MONORAIL™ / 28 mm x 3.00 mm	Work Horse	H7493918428300
PROMUS Element™ Plus MONORAIL™ / 32 mm x 3.00 mm	Work Horse	H7493918432300
PROMUS Element™ Plus MONORAIL™ / 38 mm x 3.00 mm	Work Horse	H7493918438300
PROMUS Element™ Plus MONORAIL™ / 8 mm x 3.50 mm	Work Horse	H7493918408350
PROMUS Element™ Plus MONORAIL™ / 12 mm x 3.50 mm	Work Horse	H7493918412350
PROMUS Element™ Plus MONORAIL™ / 16 mm x 3.50 mm	Work Horse	H7493918416350
PROMUS Element™ Plus MONORAIL™ / 20 mm x 3.50 mm	Work Horse	H7493918420350
PROMUS Element™ Plus MONORAIL™ / 24 mm x 3.50 mm	Work Horse	H7493918424350

Product Name / Size (Length x diameter)	Model	UPN
PROMUS Element™ Plus MONORAIL™ / 28 mm x 3.50 mm	Work Horse	H7493918428350
PROMUS Element™ Plus MONORAIL™ / 32 mm x 3.50 mm	Work Horse	H7493918432350
PROMUS Element™ Plus MONORAIL™ / 38 mm x 3.50 mm	Work Horse	H7493918438350
PROMUS Element™ Plus MONORAIL™ / 8 mm x 4.00 mm	Large Vessel	H7493918408400
PROMUS Element™ Plus MONORAIL™ / 12 mm x 4.00 mm	Large Vessel	H7493918412400
PROMUS Element™ Plus MONORAIL™ / 16 mm x 4.00 mm	Large Vessel	H7493918416400
PROMUS Element™ Plus MONORAIL™ / 20 mm x 4.00 mm	Large Vessel	H7493918420400
PROMUS Element™ Plus MONORAIL™ / 24 mm x 4.00 mm	Large Vessel	H7493918424400
PROMUS Element™ Plus MONORAIL™ / 28 mm x 4.00 mm	Large Vessel	H7493918428400
PROMUS Element™ Plus MONORAIL™ / 32 mm x 4.00 mm	Large Vessel	H7493918432400
PROMUS Element™ Plus MONORAIL™ / 38 mm x 4.00 mm	Large Vessel	H7493918438400