

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

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

Products: Promus PREMIER™ MONORAIL™ Everolimus-Eluting
Platinum Chromium 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: 7 February 2013

Signatures, Date of Issue:

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

Signature: John Donohue **Date:** 22 MAR 2013

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

Signature: Robbie Walsh **Date:** 21 March 2013

ATTACHMENT 1

Promus PREMIER™ MONORAIL™ Everolimus-Eluting Platinum Chromium Coronary Stent System
Universal Part Numbers are listed below.

Product Name / Size (Length x diameter)	Model	UPN
Promus PREMIER™ MONORAIL™ / 8 mm x 2.25 mm	Small Vessel	H7493925108220
Promus PREMIER™ MONORAIL™ / 12 mm x 2.25 mm	Small Vessel	H7493925112220
Promus PREMIER™ MONORAIL™ / 16 mm x 2.25 mm	Small Vessel	H7493925116220
Promus PREMIER™ MONORAIL™ / 20 mm x 2.25 mm	Small Vessel	H7493925120220
Promus PREMIER™ MONORAIL™ / 24 mm x 2.25 mm	Small Vessel	H7493925124220
Promus PREMIER™ MONORAIL™ / 28 mm x 2.25 mm	Small Vessel	H7493925128220
Promus PREMIER™ MONORAIL™ / 32 mm x 2.25 mm	Small Vessel	H7493925132220
Promus PREMIER™ MONORAIL™ / 8 mm x 2.50 mm	Small Work Horse	H7493925108250
Promus PREMIER™ MONORAIL™ / 12 mm x 2.50 mm	Small Work Horse	H7493925112250
Promus PREMIER™ MONORAIL™ / 16 mm x 2.50 mm	Small Work Horse	H7493925116250
Promus PREMIER™ MONORAIL™ / 20 mm x 2.50 mm	Small Work Horse	H7493925120250
Promus PREMIER™ MONORAIL™ / 24 mm x 2.50 mm	Small Work Horse	H7493925124250
Promus PREMIER™ MONORAIL™ / 28 mm x 2.50 mm	Small Work Horse	H7493925128250
Promus PREMIER™ Monorail™ / 32 mm x 2.50 mm	Small Work Horse	H7493925132250
Promus PREMIER™ MONORAIL™ / 38 mm x 2.50 mm	Small Work Horse	H7493925138250
Promus PREMIER™ MONORAIL™ / 8 mm x 2.75 mm	Small Work Horse	H7493925108270
Promus PREMIER™ MONORAIL™ / 12 mm x 2.75 mm	Small Work Horse	H7493925112270
Promus PREMIER™ MONORAIL™ / 16 mm x 2.75 mm	Small Work Horse	H7493925116270
Promus PREMIER™ MONORAIL™ / 20 mm x 2.75 mm	Small Work Horse	H7493925120270
Promus PREMIER™ MONORAIL™ / 24 mm x 2.75 mm	Small Work Horse	H7493925124270
Promus PREMIER™ MONORAIL™ / 28 mm x 2.75 mm	Small Work Horse	H7493925128270
Promus PREMIER™ MONORAIL™ / 32 mm x 2.75 mm	Small Work Horse	H7493925132270
Promus PREMIER™ MONORAIL™ / 38 mm x 2.75 mm	Small Work Horse	H7493925138270
Promus PREMIER™ MONORAIL™ / 8 mm x 3.00 mm	Work Horse	H7493925108300
Promus PREMIER™ MONORAIL™ / 12 mm x 3.00 mm	Work Horse	H7493925112300
Promus PREMIER™ MONORAIL™ / 16 mm x 3.00 mm	Work Horse	H7493925116300

Product Name / Size (Length x diameter)	Model	UPN
Promus PREMIER™ MONORAIL™ / 20 mm x 3.00 mm	Work Horse	H7493925120300
Promus PREMIER™ MONORAIL™ / 24 mm x 3.00 mm	Work Horse	H7493925124300
Promus PREMIER™ MONORAIL™ / 28 mm x 3.00 mm	Work Horse	H7493925128300
Promus PREMIER™ MONORAIL™ / 32 mm x 3.00 mm	Work Horse	H7493925132300
Promus PREMIER™ MONORAIL™ / 38 mm x 3.00 mm	Work Horse	H7493925138300
Promus PREMIER™ MONORAIL™ / 8 mm x 3.50 mm	Work Horse	H7493925108350
Promus PREMIER™ MONORAIL™ / 12 mm x 3.50 mm	Work Horse	H7493925112350
Promus PREMIER™ MONORAIL™ / 16 mm x 3.50 mm	Work Horse	H7493925116350
Promus PREMIER™ MONORAIL™ / 20 mm x 3.50 mm	Work Horse	H7493925120350
Promus PREMIER™ MONORAIL™ / 24 mm x 3.50 mm	Work Horse	H7493925124350
Promus PREMIER™ MONORAIL™ / 28 mm x 3.50 mm	Work Horse	H7493925128350
Promus PREMIER™ MONORAIL™ / 32 mm x 3.50 mm	Work Horse	H7493925132350
Promus PREMIER™ MONORAIL™ / 38 mm x 3.50 mm	Work Horse	H7493925138350
Promus PREMIER™ MONORAIL™ / 8 mm x 4.00 mm	Large Vessel	H7493925108400
Promus PREMIER™ MONORAIL™ / 12 mm x 4.00 mm	Large Vessel	H7493925112400
Promus PREMIER™ MONORAIL™ / 16 mm x 4.00 mm	Large Vessel	H7493925116400
Promus PREMIER™ MONORAIL™ / 20 mm x 4.00 mm	Large Vessel	H7493925120400
Promus PREMIER™ MONORAIL™ / 24 mm x 4.00 mm	Large Vessel	H7493925124400
Promus PREMIER™ MONORAIL™ / 28 mm x 4.00 mm	Large Vessel	H7493925128400
Promus PREMIER™ MONORAIL™ / 32 mm x 4.00 mm	Large Vessel	H7493925132400
Promus PREMIER™ MONORAIL™ / 38 mm x 4.00 mm	Large Vessel	H7493925138400