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EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA
Manufacturing Site(s):	Boston Scientific Limited Ballybrit Business Park Galway IRELAND
EU Authorized Representative:	Boston Scientific Limited Ballybrit Business Park Galway IRELAND
Product Name:	Promus ELITE™ MONORAIL™ Everolimus-Eluting Platinum Chromium Coronary Stent System (Design Dossier GAL-DD-90453488) See Attachment A- Model Designation List
Classification:	Class III, Rule 8 & 13 according to Annex IX of the MDD – 93/42/EEC

Notified Body:**DEKRA Certification B.V.**

Meander 1051
6825 MJ Arnhem
P.O. Box 5185
6802 ED Arnhem
The Netherlands

Identification Number: 0344

EC Certificates	
Certificate Name	Certificate Number
Annex II.3	3812454CE01
Annex II.4	3812454DE43
EN ISO 13485:2016	3818536

All BSC SAP manufactured products are released per Corp Form Product Shipment Release Requirements, 90213259.

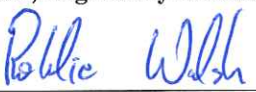
We declare that the products identified above are in conformity with all relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices. This declaration is made under Annex II of this directive. All supporting information is retained under the control of the Legal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

Name: Ann Evans
Title: Director, Quality Assurance

Signature: 

Date 30 April 2018

Name: Robbie Walsh
Title: Director, Regulatory Affairs

Signature: 

Date 30 April 2018

Attachment A- Model Designation List

Date of CE Marking: *refer to the signature page [page 2]*

Table 1: Promus ELITE™ MONORAIL™ Everolimus-Eluting Platinum Chromium Coronary Stent System Universal Part Numbers are listed below.

Unique Part Number	Material Description	GTIN Assigned
H7493941308220	P ELITE OUS MR 2.25 X 8MM	08714729971979
H7493941308250	P ELITE OUS MR 2.50 X 8MM	08714729971986
H7493941308270	P ELITE OUS MR 2.75 X 8MM	08714729971993
H7493941308300	P ELITE OUS MR 3.00 X 8MM	08714729972006
H7493941308350	P ELITE OUS MR 3.50 X 8MM	08714729972013
H7493941308400	P ELITE OUS MR 4.00 X 8MM	08714729972020
H7493941312220	P ELITE OUS MR 2.25 X 12MM	08714729972037
H7493941312250	P ELITE OUS MR 2.50 X 12MM	08714729972044
H7493941312270	P ELITE OUS MR 2.75 X 12MM	08714729972051
H7493941312300	P ELITE OUS MR 3.00 X 12MM	08714729972068
H7493941312350	P ELITE OUS MR 3.50 X 12MM	08714729972075
H7493941312400	P ELITE OUS MR 4.00 X 12MM	08714729972082
H7493941316220	P ELITE OUS MR 2.25 X 16MM	08714729972099
H7493941316250	P ELITE OUS MR 2.50 X 16MM	08714729972105
H7493941316270	P ELITE OUS MR 2.75 X 16MM	08714729972112
H7493941316300	P ELITE OUS MR 3.00 X 16MM	08714729972129
H7493941316350	P ELITE OUS MR 3.50 X 16MM	08714729972136
H7493941316400	P ELITE OUS MR 4.00 X 16MM	08714729972143
H7493941320220	P ELITE OUS MR 2.25 X 20MM	08714729972150
H7493941320250	P ELITE OUS MR 2.50 X 20MM	08714729972167
H7493941320270	P ELITE OUS MR 2.75 X 20MM	08714729972174
H7493941320300	P ELITE OUS MR 3.00 X 20MM	08714729972181
H7493941320350	P ELITE OUS MR 3.50 X 20MM	08714729972198
H7493941320400	P ELITE OUS MR 4.00 X 20MM	08714729972204
H7493941324220	P ELITE OUS MR 2.25 X 24MM	08714729972211
H7493941324250	P ELITE OUS MR 2.50 X 24MM	08714729972228
H7493941324270	P ELITE OUS MR 2.75 X 24MM	08714729972235
H7493941324300	P ELITE OUS MR 3.00 X 24MM	08714729972242
H7493941324350	P ELITE OUS MR 3.50 X 24MM	08714729972259
H7493941324400	P ELITE OUS MR 4.00 X 24MM	08714729972266

Unique Part Number	Material Description	GTIN Assigned
H7493941328220	P ELITE OUS MR 2.25 X 28MM	08714729972273
H7493941328250	P ELITE OUS MR 2.50 X 28MM	08714729972280
H7493941328270	P ELITE OUS MR 2.75 X 28MM	08714729972297
H7493941328300	P ELITE OUS MR 3.00 X 28MM	08714729972303
H7493941328350	P ELITE OUS MR 3.50 X 28MM	08714729972310
H7493941328400	P ELITE OUS MR 4.00 X 28MM	08714729972327
H7493941332220	P ELITE OUS MR 2.25 X 32MM	08714729972334
H7493941332250	P ELITE OUS MR 2.50 X 32MM	08714729972341
H7493941332270	P ELITE OUS MR 2.75 X 32MM	08714729972358
H7493941332300	P ELITE OUS MR 3.00 X 32MM	08714729972365
H7493941332350	P ELITE OUS MR 3.50 X 32MM	08714729972372
H7493941332400	P ELITE OUS MR 4.00 X 32MM	08714729972389
H7493941338250	P ELITE OUS MR 2.50 X 38MM	08714729972396
H7493941338270	P ELITE OUS MR 2.75 X 38MM	08714729972402
H7493941338300	P ELITE OUS MR 3.00 X 38MM	08714729972419
H7493941338350	P ELITE OUS MR 3.50 X 38MM	08714729972426
H7493941338400	P ELITE OUS MR 4.00 X 38MM	08714729972433