

EC DESIGN-EXAMINATION CERTIFICATE

Number: 3812454DE43

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

Boston Scientific Corporation

**300 Boston Scientific Way
Marlborough, MA 01752
United States Of America**

For the product

Promus Elite™ Everolimus-Eluting Platinum Chromium Coronary Stent System

Documents, that form the basis of this certificate:

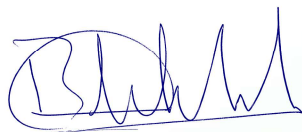
Certification Notice 3812454CN, initially dated 1 July 2014
Addendum, initially dated 28 March 2018

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 28 March 2018
Reissued: 6 September 2019

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 3812454DE43

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Promus Elite™ Everolimus-Eluting Platinum Chromium Coronary Stent System

Issued to:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
United States Of America

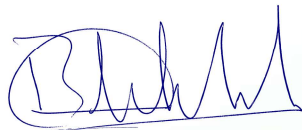
This certificate covers the following product(s):

Name	Model	Sizes (Lengths x Diameters)
PROMUS Elite™	Small Vessel	8 mm x 2.25 mm to 32 mm x 2.25 mm
PROMUS Elite™	Small Work Horse	8 mm x 2.50 mm to 38 mm x 2.50 mm
PROMUS Elite™	Small Work Horse	8 mm x 2.75 mm to 38 mm x 2.75 mm
PROMUS Elite™	Work Horse	8 mm x 3.00 mm to 38 mm x 3.00 mm
PROMUS Elite™	Work Horse	8 mm x 3.50 mm to 38 mm x 3.50 mm
PROMUS Elite™	Large Vessel	8 mm x 4.00 mm to 38 mm x 4.00 mm

Initial date: 28 March 2018

Revision date: 3 April 2020

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B.T.M. Holtus
Managing Director



J.A. van Vugt
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