

EC DESIGN-EXAMINATION CERTIFICATE

Number: 3812454DE06

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 Element™ MONORAIL™ Everolimus-Eluting Coronary Stent System
PROMUS Element™ Long MONORAIL™ Everolimus-Eluting Coronary Stent System
PROMUS Element™ Plus MONORAIL™ Everolimus-Eluting Coronary Stent System
Promus PREMIER™ MONORAIL™ Everolimus-Eluting Platinum Chromium Coronary Stent System**

Documents, that form the basis of this certificate:

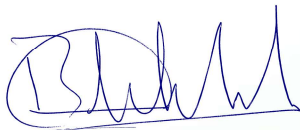
**Certification Notice 3812454CN, initially dated 1 July 2014
Addendum, initially dated 1 July 2014**

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: 1 July 2014
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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 3812454DE06

1/3

EC DESIGN-EXAMINATION MEDICAL DEVICES

PROMUS Element™ MONORAIL™ Everolimus-Eluting Coronary Stent System
PROMUS Element™ Long MONORAIL™ Everolimus-Eluting Coronary Stent System
PROMUS Element™ Plus MONORAIL™ Everolimus-Eluting Coronary Stent System
Promus PREMIER™ MONORAIL™ Everolimus-Eluting Platinum Chromium Coronary Stent System

Issued to:

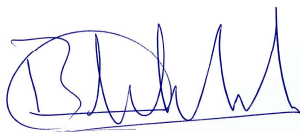
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
United States Of America

This certificate covers the following product(s):

Name	Models	Sizes (Lengths x Diameters)
PROMUS Element™ MONORAIL™	SV	8 mm x 2.25 mm to 32 mm x 2.25 mm
PROMUS Element™ MONORAIL™	SWH	8 mm x 2.50 mm to 32 mm x 2.50 mm
PROMUS Element™ MONORAIL™	SWH	8 mm x 2.75 mm to 32 mm x 2.75 mm
PROMUS Element™ MONORAIL™	WH	8 mm x 3.00 mm to 32 mm x 3.00 mm
PROMUS Element™ MONORAIL™	WH	8 mm x 3.50 mm to 32 mm x 3.50 mm
PROMUS Element™ MONORAIL™	LV	8 mm x 4.00 mm to 32 mm x 4.00 mm

Name	Models	Sizes (Lengths x Diameters)
PROMUS Element™ Long MONORAIL™	SWH	38 mm x 2.50 mm
PROMUS Element™ Long MONORAIL™	SWH	38 mm x 2.75 mm
PROMUS Element™ Long MONORAIL™	WH	38 mm x 3.00 mm
PROMUS Element™ Long MONORAIL™	WH	38 mm x 3.50 mm
PROMUS Element™ Long MONORAIL™	LV	38 mm x 4.00 mm

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B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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EC DESIGN-EXAMINATION MEDICAL DEVICES

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 PROMUS Element™ Long MONORAIL™ Everolimus-Eluting Coronary Stent System
 PROMUS Element™ Plus MONORAIL™ Everolimus-Eluting Coronary Stent System - see cert

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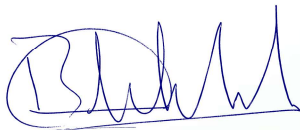
Boston Scientific Corporation
 300 Boston Scientific Way
 Marlborough, MA 01752
 United States Of America

This certificate covers the following product(s): continued:

Name	Models	Sizes (Lengths x Diameters)
PROMUS Element™ Plus MONORAIL™	SV	8 mm x 2.25 mm to 32 mm x 2.25 mm
PROMUS Element™ Plus MONORAIL™	SWH	8 mm x 2.50 mm to 38 mm x 2.50 mm
PROMUS Element™ Plus MONORAIL™	SWH	8 mm x 2.75 mm to 38 mm x 2.75 mm
PROMUS Element™ Plus MONORAIL™	WH	8 mm x 3.00 mm to 38 mm x 3.00 mm
PROMUS Element™ Plus MONORAIL™	WH	8 mm x 3.50 mm to 38 mm x 3.50 mm
PROMUS Element™ Plus MONORAIL™	LV	8 mm x 4.00 mm to 38 mm x 4.00 mm

Name	Models	Sizes (Lengths x Diameters)
Promus PREMIER™ MONORAIL™	SV	8 mm x 2.25 mm to 32 mm x 2.25 mm
Promus PREMIER™ MONORAIL™	SWH	8 mm x 2.50 mm to 38 mm x 2.50 mm
Promus PREMIER™ MONORAIL™	SWH	8 mm x 2.75 mm to 38 mm x 2.75 mm
Promus PREMIER™ MONORAIL™	WH	8 mm x 3.00 mm to 38 mm x 3.00 mm
Promus PREMIER™ MONORAIL™	WH	8 mm x 3.50 mm to 38 mm x 3.50 mm
Promus PREMIER™ MONORAIL™	LV	8 mm x 4.00 mm to 38 mm x 4.00 mm

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B.T.M. Holtus
 Managing Director



J.A. van Vugt
 Certification Manager

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EC DESIGN-EXAMINATION MEDICAL DEVICES

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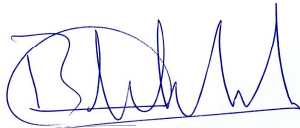
Issued to:

Boston Scientific Corporation

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

Initial date: 1 July 2014
Revision date: 3 April 2020

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, written in a cursive style.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, written in a cursive style.

J.A. van Vugt
Certification Manager

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