

EC DESIGN-EXAMINATION CERTIFICATE

Number: 3812454DE39

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

Comet Pressure Guidewire

Documents, that form the basis of this certificate:

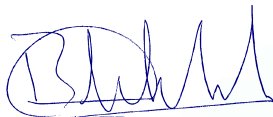
Certification Notice 3812454CN, initially dated 1 July 2014
Addendum, initially dated 10 February 2016

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: 10 February 2016
Reissued: 26 July 2019

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized initials and a surname.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, consisting of stylized initials and a surname.

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: 3812454DE39

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Comet Pressure Guidewire

Issued to:

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

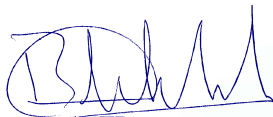
This certificate covers the following product(s):

Name	Sizes
Comet™ Pressure Guidewire	185 cm length, 0.36mm diameter
Comet™ II Pressure Guidewire	185 cm length, 0.36mm diameter

Initial date: 10 February 2016

Revision date: 3 April 2020

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

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