

EC DESIGN-EXAMINATION CERTIFICATE

Number: 3812454DE17

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

Apex™ Flex MONORAIL™ PTCA Dilatation Catheter
Apex™ Flex OVER-THE-WIRE PTCA Dilatation Catheter
Apex™ Push MONORAIL™ PTCA Dilatation Catheter
Apex™ Push OVER-THE-WIRE PTCA Dilatation Catheter
Apex™ MONORAIL™ PTCA Dilatation Catheter
Apex™ OVER-THE-WIRE PTCA Dilatation Catheter

Documents, that form the basis of this certificate:

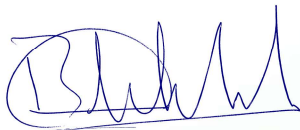
Certification Notice 3812454CN, initially dated 1 July 2014
Addendum, initially dated 1 July 2014

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: 12 March 2020

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: 3812454DE17

1/1

EC DESIGN-EXAMINATION MEDICAL DEVICES

Apex™ Flex MONORAIL™ PTCA Dilatation Catheter
Apex™ Flex OVER-THE-WIRE PTCA Dilatation Catheter
Apex™ Push MONORAIL™ PTCA Dilatation Catheter
Apex™ Push OVER-THE-WIRE PTCA Dilatation Catheter
Apex™ MONORAIL™ PTCA Dilatation Catheter
Apex™ OVER-THE-WIRE PTCA Dilatation Catheter

Issued to:

Boston Scientific Corporation

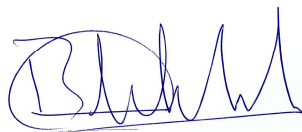
**300 Boston Scientific Way
Marlborough, MA 01752
United States Of America**

This certificate covers the following products:

Name	Diameters	Lengths
Apex™ Flex MONORAIL™	1.50mm	8mm through 20mm
Apex™ Flex OVER-THE-WIRE	1.50mm	8mm through 20mm
Apex™ Push MONORAIL™	1.50mm	8mm through 20mm
Apex™ Push OVER-THE-WIRE	1.50mm	8mm through 20mm
Apex™ MONORAIL™	2.00mm through 5.00mm	8mm through 40mm
Apex™ OVER-THE-WIRE	2.00mm through 5.00mm	8mm through 40mm

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

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