



Boston Scientific Corporation  
300 Boston Scientific Way  
Marlborough, MA 01752  
(508) 382-4000  
www.bostonscientific.com

## EC DECLARATION OF CONFORMITY

**Legal Manufacturer:** Boston Scientific Corporation  
300 Boston Scientific Way  
Marlborough, MA 01752  
USA

**Manufacturing Site:** Boston Scientific Limited  
Ballybrit Business Park  
Galway  
IRELAND

**EU Authorized Representative:** Boston Scientific Limited  
Ballybrit Business Park  
Galway  
IRELAND

**Product Name:** **SYNERGY™ MONORAIL™ / SYNERGY  
MEGATRON™ / SYNERGY™ XD  
Everolimus-Eluting Platinum Chromium  
Coronary Stent System**  
Design Dossier: GAL-DD-90710065  
See Attachment A for Model Designations.

**Classification:** Class III, Rules 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

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MANUFACTURE OR SALE OF APPARATUS WITHOUT THE EXPRESS WRITTEN CONSENT OF BOSTON SCIENTIFIC CORP.

Boston Scientific  
EC Declaration of Conformity  
**SYNERGY MONORAIL PRODUCT FAMILIES**  
90967103 Rev/Ver AM  
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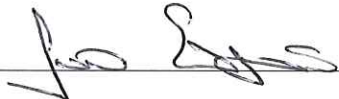
| EC Certificates   |                            |
|---|----------------------------|
| Certificate Name  | Certificate Numbers        |
| DEKRA Full Quality Assurance Certificate                | 3812454CE01                |
| DEKRA EC Design-Examination Certificate                 | 3812454DE32<br>3812454DE46 |
| DEKRA Management System Certificate - 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.


**Signature, Date of Issue:**

**Name:** Ann Evans  
**Title:** Director, Quality Assurance

**Signature:**  \_\_\_\_\_

**Date:** 14/Jan/2020

**Name:** Robbie Walsh  
**Title:** Director, Regulatory Affairs

**Signature:**  \_\_\_\_\_

**Date:** 14/Jan/2020

## ATTACHMENT A

### Model Designation Summary

SYNERGY MONORAIL Everolimus-Eluting Platinum Chromium Coronary Stent System

**Date of CE Marking (8-38mm lengths):** 25 November 2013

**Date of CE Marking (48mm lengths):** 9 January 2017

**Date of CE Marking (4.50 and 5.00mm diameters):** 8 August 2018

**Date of CE Marking SYNERGY MEGATRON (8-32mm lengths; 3.50-5.00mm diameters):** 24 September 2019

**Date of CE Marking SYNERGY XD (8-48mm lengths; 2.25-5.00mm diameters):** refer to signatures on page 2.

| Product Name / Size (Length x diameter) | Model        | UPN            | GTIN           |
|---|--------------|----------------|----------------|
| SYNERGY MONORAIL / 8 mm x 2.25 mm       | Small Vessel | H7493926208220 | 08714729840923 |
| SYNERGY MONORAIL / 12 mm x 2.25 mm      | Small Vessel | H7493926212220 | 08714729840985 |
| SYNERGY MONORAIL / 16 mm x 2.25 mm      | Small Vessel | H7493926216220 | 08714729841043 |
| SYNERGY MONORAIL / 20 mm x 2.25 mm      | Small Vessel | H7493926220220 | 08714729841104 |
| SYNERGY MONORAIL / 24 mm x 2.25 mm      | Small Vessel | H7493926224220 | 08714729841166 |
| SYNERGY MONORAIL / 28 mm x 2.25 mm      | Small Vessel | H7493926228220 | 08714729841227 |
| SYNERGY MONORAIL / 32 mm x 2.25 mm      | Small Vessel | H7493926232220 | 08714729841289 |
| SYNERGY MONORAIL / 38 mm x 2.25 mm      | Small Vessel | H7493926238220 | 08714729841340 |
| SYNERGY MONORAIL / 8 mm x 2.50 mm       | Small Vessel | H7493926208250 | 08714729840930 |
| SYNERGY MONORAIL / 12 mm x 2.50 mm      | Small Vessel | H7493926212250 | 08714729840992 |
| SYNERGY MONORAIL / 16 mm x 2.50 mm      | Small Vessel | H7493926216250 | 08714729841050 |
| SYNERGY MONORAIL / 20 mm x 2.50 mm      | Small Vessel | H7493926220250 | 08714729841111 |
| SYNERGY MONORAIL / 24 mm x 2.50 mm      | Small Vessel | H7493926224250 | 08714729841173 |
| SYNERGY MONORAIL / 28 mm x 2.50 mm      | Small Vessel | H7493926228250 | 08714729841234 |
| SYNERGY MONORAIL / 32 mm x 2.50 mm      | Small Vessel | H7493926232250 | 08714729841296 |
| SYNERGY MONORAIL / 38 mm x 2.50 mm      | Small Vessel | H7493926238250 | 08714729841357 |
| SYNERGY MONORAIL / 48 mm x 2.50 mm      | Small Vessel | H7493926248250 | 08714729935612 |
| SYNERGY MONORAIL / 8 mm x 2.75 mm       | Small Vessel | H7493926208270 | 08714729840947 |
| SYNERGY MONORAIL / 12 mm x 2.75 mm      | Small Vessel | H7493926212270 | 08714729841005 |
| SYNERGY MONORAIL / 16 mm x 2.75 mm      | Small Vessel | H7493926216270 | 08714729841067 |



| Product Name / Size (Length x diameter) | Model        | UPN            | GTIN           |
|---|--------------|----------------|----------------|
| SYNERGY MONORAIL / 20 mm x 2.75 mm      | Small Vessel | H7493926220270 | 08714729841128 |
| SYNERGY MONORAIL / 24 mm x 2.75 mm      | Small Vessel | H7493926224270 | 08714729841180 |
| SYNERGY MONORAIL / 28 mm x 2.75 mm      | Small Vessel | H7493926228270 | 08714729841241 |
| SYNERGY MONORAIL / 32 mm x 2.75 mm      | Small Vessel | H7493926232270 | 08714729841302 |
| SYNERGY MONORAIL / 38 mm x 2.75 mm      | Small Vessel | H7493926238270 | 08714729841364 |
| SYNERGY MONORAIL / 48 mm x 2.75 mm      | Small Vessel | H7493926248270 | 08714729935629 |
| SYNERGY MONORAIL / 8 mm x 3.00 mm       | Work Horse   | H7493926208300 | 08714729840954 |
| SYNERGY MONORAIL / 12 mm x 3.00 mm      | Work Horse   | H7493926212300 | 08714729841012 |
| SYNERGY MONORAIL / 16 mm x 3.00 mm      | Work Horse   | H7493926216300 | 08714729841074 |
| SYNERGY MONORAIL / 20 mm x 3.00 mm      | Work Horse   | H7493926220300 | 08714729841135 |
| SYNERGY MONORAIL / 24 mm x 3.00 mm      | Work Horse   | H7493926224300 | 08714729841197 |
| SYNERGY MONORAIL / 28 mm x 3.00 mm      | Work Horse   | H7493926228300 | 08714729841258 |
| SYNERGY MONORAIL / 32 mm x 3.00 mm      | Work Horse   | H7493926232300 | 08714729841319 |
| SYNERGY MONORAIL / 38 mm x 3.00 mm      | Work Horse   | H7493926238300 | 08714729841371 |
| SYNERGY MONORAIL / 48 mm x 3.00 mm      | Work Horse   | H7493926248300 | 08714729935636 |
| SYNERGY MONORAIL / 8 mm x 3.50 mm       | Work Horse   | H7493926208350 | 08714729840961 |
| SYNERGY MONORAIL / 12 mm x 3.50 mm      | Work Horse   | H7493926212350 | 08714729841029 |
| SYNERGY MONORAIL / 16 mm x 3.50 mm      | Work Horse   | H7493926216350 | 08714729841081 |
| SYNERGY MONORAIL / 20 mm x 3.50 mm      | Work Horse   | H7493926220350 | 08714729841142 |
| SYNERGY MONORAIL / 24 mm x 3.50 mm      | Work Horse   | H7493926224350 | 08714729841203 |
| SYNERGY MONORAIL / 28 mm x 3.50 mm      | Work Horse   | H7493926228350 | 08714729841265 |
| SYNERGY MONORAIL / 32 mm x 3.50 mm      | Work Horse   | H7493926232350 | 08714729841326 |
| SYNERGY MONORAIL / 38 mm x 3.50 mm      | Work Horse   | H7493926238350 | 08714729841388 |
| SYNERGY MONORAIL / 48 mm x 3.50 mm      | Work Horse   | H7493926248350 | 08714729935643 |
| SYNERGY MONORAIL / 8 mm x 4.00 mm       | Large Vessel | H7493926208400 | 08714729840978 |
| SYNERGY MONORAIL / 12 mm x 4.00 mm      | Large Vessel | H7493926212400 | 08714729841036 |
| SYNERGY MONORAIL / 16 mm x 4.00 mm      | Large Vessel | H7493926216400 | 08714729841098 |
| SYNERGY MONORAIL / 20 mm x 4.00 mm      | Large Vessel | H7493926220400 | 08714729841159 |
| SYNERGY MONORAIL / 24 mm x 4.00 mm      | Large Vessel | H7493926224400 | 08714729841210 |

| Product Name / Size (Length x diameter)     | Model              | UPN            | GTIN           |
|---|--------------------|----------------|----------------|
| SYNERGY MONORAIL / 28 mm x 4.00 mm          | Large Vessel       | H7493926228400 | 08714729841272 |
| SYNERGY MONORAIL / 32 mm x 4.00 mm          | Large Vessel       | H7493926232400 | 08714729841333 |
| SYNERGY MONORAIL / 38 mm x 4.00 mm          | Large Vessel       | H7493926238400 | 08714729841395 |
| SYNERGY MONORAIL / 48 mm x 4.00 mm          | Large Vessel       | H7493926248400 | 08714729935650 |
| SYNERGY MONORAIL / 12 mm x 4.50 mm          | Large Vessel       | H7493926212450 | 08714729974321 |
| SYNERGY MONORAIL / 16 mm x 4.50 mm          | Large Vessel       | H7493926216450 | 08714729974338 |
| SYNERGY MONORAIL / 20 mm x 4.50 mm          | Large Vessel       | H7493926220450 | 08714729974345 |
| SYNERGY MONORAIL / 24 mm x 4.50 mm          | Large Vessel       | H7493926224450 | 08714729974352 |
| SYNERGY MONORAIL / 28 mm x 4.50 mm          | Large Vessel       | H7493926228450 | 08714729974369 |
| SYNERGY MONORAIL / 32 mm x 4.50 mm          | Large Vessel       | H7493926232450 | 08714729974376 |
| SYNERGY MONORAIL / 12 mm x 5.00 mm          | Large Vessel       | H7493926212500 | 08714729974406 |
| SYNERGY MONORAIL / 16 mm x 5.00 mm          | Large Vessel       | H7493926216500 | 08714729974413 |
| SYNERGY MONORAIL / 20 mm x 5.00 mm          | Large Vessel       | H7493926220500 | 08714729974420 |
| SYNERGY MONORAIL / 24 mm x 5.00 mm          | Large Vessel       | H7493926224500 | 08714729974437 |
| SYNERGY MONORAIL / 28 mm x 5.00 mm          | Large Vessel       | H7493926228500 | 08714729974444 |
| SYNERGY MONORAIL / 32 mm x 5.00 mm          | Large Vessel       | H7493926232500 | 08714729974451 |
| SYNERGY MEGATRON MONORAIL / 3.50 mm x 8 mm  | Extra Large Vessel | H7493942708350 | 08714729985259 |
| SYNERGY MEGATRON MONORAIL / 4.00 mm x 8 mm  | Extra Large Vessel | H7493942708400 | 08714729985266 |
| SYNERGY MEGATRON MONORAIL / 4.50 mm x 8 mm  | Extra Large Vessel | H7493942708450 | 08714729985273 |
| SYNERGY MEGATRON MONORAIL / 5.00 mm x 8 mm  | Extra Large Vessel | H7493942708500 | 08714729985280 |
| SYNERGY MEGATRON MONORAIL / 3.50 mm x 12 mm | Extra Large Vessel | H7493942712350 | 08714729985297 |
| SYNERGY MEGATRON MONORAIL / 4.00 mm x 12 mm | Extra Large Vessel | H7493942712400 | 08714729985303 |
| SYNERGY MEGATRON MONORAIL / 4.50 mm x 12 mm | Extra Large Vessel | H7493942712450 | 08714729985310 |
| SYNERGY MEGATRON MONORAIL / 5.00 mm x 12 mm | Extra Large Vessel | H7493942712500 | 08714729985327 |
| SYNERGY MEGATRON MONORAIL / 3.50 mm x 16 mm | Extra Large Vessel | H7493942716350 | 08714729985334 |



| Product Name / Size (Length x diameter)     | Model              | UPN            | GTIN           |
|---|--------------------|----------------|----------------|
| SYNERGY MEGATRON MONORAIL / 4.00 mm x 16 mm | Extra Large Vessel | H7493942716400 | 08714729985341 |
| SYNERGY MEGATRON MONORAIL / 4.50 mm x 16 mm | Extra Large Vessel | H7493942716450 | 08714729985358 |
| SYNERGY MEGATRON MONORAIL / 5.00 mm x 16 mm | Extra Large Vessel | H7493942716500 | 08714729985365 |
| SYNERGY MEGATRON MONORAIL / 3.50 mm x 20 mm | Extra Large Vessel | H7493942720350 | 08714729985372 |
| SYNERGY MEGATRON MONORAIL / 4.00 mm x 20 mm | Extra Large Vessel | H7493942720400 | 08714729985389 |
| SYNERGY MEGATRON MONORAIL / 4.50 mm x 20 mm | Extra Large Vessel | H7493942720450 | 08714729985396 |
| SYNERGY MEGATRON MONORAIL / 5.00 mm x 20 mm | Extra Large Vessel | H7493942720500 | 08714729985402 |
| SYNERGY MEGATRON MONORAIL / 3.50 mm x 24 mm | Extra Large Vessel | H7493942724350 | 08714729985419 |
| SYNERGY MEGATRON MONORAIL / 4.00 mm x 24 mm | Extra Large Vessel | H7493942724400 | 08714729985426 |
| SYNERGY MEGATRON MONORAIL / 4.50 mm x 24 mm | Extra Large Vessel | H7493942724450 | 08714729985433 |
| SYNERGY MEGATRON MONORAIL / 5.00 mm x 24 mm | Extra Large Vessel | H7493942724500 | 08714729985440 |
| SYNERGY MEGATRON MONORAIL / 3.50 mm x 28 mm | Extra Large Vessel | H7493942728350 | 08714729985457 |
| SYNERGY MEGATRON MONORAIL / 4.00 mm x 28 mm | Extra Large Vessel | H7493942728400 | 08714729985464 |
| SYNERGY MEGATRON MONORAIL / 4.50 mm x 28 mm | Extra Large Vessel | H7493942728450 | 08714729985471 |
| SYNERGY MEGATRON MONORAIL / 5.00 mm x 28 mm | Extra Large Vessel | H7493942728500 | 08714729985488 |
| SYNERGY MEGATRON MONORAIL / 3.50 mm x 32 mm | Extra Large Vessel | H7493942732350 | 08714729985495 |
| SYNERGY MEGATRON MONORAIL / 4.00 mm x 32 mm | Extra Large Vessel | H7493942732400 | 08714729985501 |
| SYNERGY MEGATRON MONORAIL / 4.50 mm x 32 mm | Extra Large Vessel | H7493942732450 | 08714729985518 |

| Product Name / Size (Length x diameter)     | Model              | UPN            | GTIN           |
|---|--------------------|----------------|----------------|
| SYNERGY MEGATRON MONORAIL / 5.00 mm x 32 mm | Extra Large Vessel | H7493942732500 | 08714729985525 |
| SYNERGY XD MONORAIL / 8 mm x 2.25 mm        | Small Vessel       | H7493941708220 | 08714729980056 |
| SYNERGY XD MONORAIL / 12 mm x 2.25 mm       | Small Vessel       | H7493941712220 | 08714729980063 |
| SYNERGY XD MONORAIL / 16 mm x 2.25 mm       | Small Vessel       | H7493941716220 | 08714729980070 |
| SYNERGY XD MONORAIL / 20 mm x 2.25 mm       | Small Vessel       | H7493941720220 | 08714729980087 |
| SYNERGY XD MONORAIL / 24 mm x 2.25 mm       | Small Vessel       | H7493941724220 | 08714729980094 |
| SYNERGY XD MONORAIL / 28 mm x 2.25 mm       | Small Vessel       | H7493941728220 | 08714729980100 |
| SYNERGY XD MONORAIL / 32 mm x 2.25 mm       | Small Vessel       | H7493941732220 | 08714729980117 |
| SYNERGY XD MONORAIL / 38 mm x 2.25 mm       | Small Vessel       | H7493941738220 | 08714729980124 |
| SYNERGY XD MONORAIL / 8 mm x 2.50 mm        | Small Vessel       | H7493941708250 | 08714729980131 |
| SYNERGY XD MONORAIL / 12 mm x 2.50 mm       | Small Vessel       | H7493941712250 | 08714729980148 |
| SYNERGY XD MONORAIL / 16 mm x 2.50 mm       | Small Vessel       | H7493941716250 | 08714729980155 |
| SYNERGY XD MONORAIL / 20 mm x 2.50 mm       | Small Vessel       | H7493941720250 | 08714729980162 |
| SYNERGY XD MONORAIL / 24 mm x 2.50 mm       | Small Vessel       | H7493941724250 | 08714729980179 |
| SYNERGY XD MONORAIL / 28 mm x 2.50 mm       | Small Vessel       | H7493941728250 | 08714729980186 |
| SYNERGY XD MONORAIL / 32 mm x 2.50 mm       | Small Vessel       | H7493941732250 | 08714729980193 |
| SYNERGY XD MONORAIL / 38 mm x 2.50 mm       | Small Vessel       | H7493941738250 | 08714729980209 |
| SYNERGY XD MONORAIL / 48 mm x 2.50 mm       | Small Vessel       | H7493941748250 | 08714729980216 |
| SYNERGY XD MONORAIL / 8 mm x 2.75 mm        | Small Vessel       | H7493941708270 | 08714729980223 |
| SYNERGY XD MONORAIL / 12 mm x 2.75 mm       | Small Vessel       | H7493941712270 | 08714729980230 |
| SYNERGY XD MONORAIL / 16 mm x 2.75 mm       | Small Vessel       | H7493941716270 | 08714729980247 |
| SYNERGY XD MONORAIL / 20 mm x 2.75 mm       | Small Vessel       | H7493941720270 | 08714729980254 |
| SYNERGY XD MONORAIL / 24 mm x 2.75 mm       | Small Vessel       | H7493941724270 | 08714729980261 |
| SYNERGY XD MONORAIL / 28 mm x 2.75 mm       | Small Vessel       | H7493941728270 | 08714729980278 |
| SYNERGY XD MONORAIL / 32 mm x 2.75 mm       | Small Vessel       | H7493941732270 | 08714729980285 |
| SYNERGY XD MONORAIL / 38 mm x 2.75 mm       | Small Vessel       | H7493941738270 | 08714729980292 |
| SYNERGY XD MONORAIL / 48 mm x 2.75 mm       | Small Vessel       | H7493941748270 | 08714729980308 |
| SYNERGY XD MONORAIL / 8 mm x 3.00 mm        | Work Horse         | H7493941708300 | 08714729980315 |
| SYNERGY XD MONORAIL / 12 mm x 3.00 mm       | Work Horse         | H7493941712300 | 08714729980322 |
| SYNERGY XD MONORAIL / 16 mm x 3.00 mm       | Work Horse         | H7493941716300 | 08714729980339 |



| Product Name / Size (Length x diameter) | Model        | UPN            | GTIN           |
|---|--------------|----------------|----------------|
| SYNERGY XD MONORAIL / 20 mm x 3.00 mm   | Work Horse   | H7493941720300 | 08714729980346 |
| SYNERGY XD MONORAIL / 24 mm x 3.00 mm   | Work Horse   | H7493941724300 | 08714729980353 |
| SYNERGY XD MONORAIL / 28 mm x 3.00 mm   | Work Horse   | H7493941728300 | 08714729980360 |
| SYNERGY XD MONORAIL / 32 mm x 3.00 mm   | Work Horse   | H7493941732300 | 08714729980377 |
| SYNERGY XD MONORAIL / 38 mm x 3.00 mm   | Work Horse   | H7493941738300 | 08714729980384 |
| SYNERGY XD MONORAIL / 48 mm x 3.00 mm   | Work Horse   | H7493941748300 | 08714729980391 |
| SYNERGY XD MONORAIL / 8 mm x 3.50 mm    | Work Horse   | H7493941708350 | 08714729980407 |
| SYNERGY XD MONORAIL / 12 mm x 3.50 mm   | Work Horse   | H7493941712350 | 08714729980414 |
| SYNERGY XD MONORAIL / 16 mm x 3.50 mm   | Work Horse   | H7493941716350 | 08714729980421 |
| SYNERGY XD MONORAIL / 20 mm x 3.50 mm   | Work Horse   | H7493941720350 | 08714729980438 |
| SYNERGY XD MONORAIL / 24 mm x 3.50 mm   | Work Horse   | H7493941724350 | 08714729980445 |
| SYNERGY XD MONORAIL / 28 mm x 3.50 mm   | Work Horse   | H7493941728350 | 08714729980452 |
| SYNERGY XD MONORAIL / 32 mm x 3.50 mm   | Work Horse   | H7493941732350 | 08714729980469 |
| SYNERGY XD MONORAIL / 38 mm x 3.50 mm   | Work Horse   | H7493941738350 | 08714729980476 |
| SYNERGY XD MONORAIL / 48 mm x 3.50 mm   | Work Horse   | H7493941748350 | 08714729980483 |
| SYNERGY XD MONORAIL / 8 mm x 4.00 mm    | Large Vessel | H7493941708400 | 08714729980490 |
| SYNERGY XD MONORAIL / 12 mm x 4.00 mm   | Large Vessel | H7493941712400 | 08714729980506 |
| SYNERGY XD MONORAIL / 16 mm x 4.00 mm   | Large Vessel | H7493941716400 | 08714729980513 |
| SYNERGY XD MONORAIL / 20 mm x 4.00 mm   | Large Vessel | H7493941720400 | 08714729980520 |
| SYNERGY XD MONORAIL / 24 mm x 4.00 mm   | Large Vessel | H7493941724400 | 08714729980537 |
| SYNERGY XD MONORAIL / 28 mm x 4.00 mm   | Large Vessel | H7493941728400 | 08714729980544 |
| SYNERGY XD MONORAIL / 32 mm x 4.00 mm   | Large Vessel | H7493941732400 | 08714729980551 |
| SYNERGY XD MONORAIL / 38 mm x 4.00 mm   | Large Vessel | H7493941738400 | 08714729980568 |
| SYNERGY XD MONORAIL / 48 mm x 4.00 mm   | Large Vessel | H7493941748400 | 08714729980575 |
| SYNERGY XD MONORAIL / 12 mm x 4.50 mm   | Large Vessel | H7493941712450 | 08714729980582 |
| SYNERGY XD MONORAIL / 16 mm x 4.50 mm   | Large Vessel | H7493941716450 | 08714729980599 |
| SYNERGY XD MONORAIL / 20 mm x 4.50 mm   | Large Vessel | H7493941720450 | 08714729980605 |
| SYNERGY XD MONORAIL / 24 mm x 4.50 mm   | Large Vessel | H7493941724450 | 08714729980612 |
| SYNERGY XD MONORAIL / 28 mm x 4.50 mm   | Large Vessel | H7493941728450 | 08714729980629 |
| SYNERGY XD MONORAIL / 32 mm x 4.50 mm   | Large Vessel | H7493941732450 | 08714729980636 |
| SYNERGY XD MONORAIL / 12 mm x 5.00 mm   | Large Vessel | H7493941712500 | 08714729980643 |



| <b>Product Name / Size (Length x diameter)</b> | <b>Model</b> | <b>UPN</b>     | <b>GTIN</b>    |
|--|--------------|----------------|----------------|
| SYNERGY XD MONORAIL / 16 mm x 5.00 mm          | Large Vessel | H7493941716500 | 08714729980650 |
| SYNERGY XD MONORAIL / 20 mm x 5.00 mm          | Large Vessel | H7493941720500 | 08714729980667 |
| SYNERGY XD MONORAIL / 24 mm x 5.00 mm          | Large Vessel | H7493941724500 | 08714729980674 |
| SYNERGY XD MONORAIL / 28 mm x 5.00 mm          | Large Vessel | H7493941728500 | 08714729980681 |
| SYNERGY XD MONORAIL / 32 mm x 5.00 mm          | Large Vessel | H7493941732500 | 08714729980698 |



# EC DESIGN-EXAMINATION CERTIFICATE

Number: 3812454DE32

**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

**SYNERGY™ MONORAIL™ and SYNERGY MEGATRON™ 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  
Revised: 23 September 2019  
Reissued: 15 April 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: 3812454DE32

1/2

## EC DESIGN-EXAMINATION MEDICAL DEVICES

SYNERGY™ MONORAIL™ and SYNERGY MEGATRON™ MONORAIL™  
Everolimus-Eluting Platinum Chromium Coronary Stent System

Issued to:

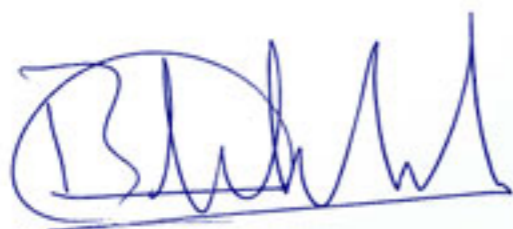
### **Boston Scientific Corporation**

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

This certificate covers the following product(s):

| Name                           | Models | Diameters | Lengths        |
|--------------------------------|--------|-----------|----------------|
| SYNERGY™ MONORAIL™             | SV     | 2.25 mm   | 8mm to 38 mm   |
| SYNERGY™ MONORAIL™             | SV     | 2.50 mm   | 8mm to 48 mm   |
| SYNERGY™ MONORAIL™             | SV     | 2.75 mm   | 8mm to 48 mm   |
| SYNERGY™ MONORAIL™             | WH     | 3.00 mm   | 8mm to 48 mm   |
| SYNERGY™ MONORAIL™             | WH     | 3.50 mm   | 8mm to 48 mm   |
| SYNERGY™ MONORAIL™             | LV     | 4.00 mm   | 8mm to 48 mm   |
| SYNERGY™ MONORAIL™             | LV     | 4.50 mm   | 12 mm to 32 mm |
| SYNERGY™ MONORAIL™             | LV     | 5.00 mm   | 12 mm to 32 mm |
| SYNERGY MEGATRON™<br>MONORAIL™ | XLV    | 3.50 mm   | 8 mm to 32 mm  |
| SYNERGY MEGATRON™<br>MONORAIL™ | XLV    | 4.00 mm   | 8 mm to 32 mm  |
| SYNERGY MEGATRON™<br>MONORAIL™ | XLV    | 4.50 mm   | 8 mm to 32 mm  |
| SYNERGY MEGATRON™<br>MONORAIL™ | XLV    | 5.00 mm   | 8 mm to 32 mm  |

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B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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# ADDENDUM

Belonging to certificate: 3812454DE32

2/2

## EC DESIGN-EXAMINATION MEDICAL DEVICES

SYNERGY™ MONORAIL™ and SYNERGY MEGATRON™ MONORAIL™ Everolimus-Eluting Platinum Chromium Coronary Stent System

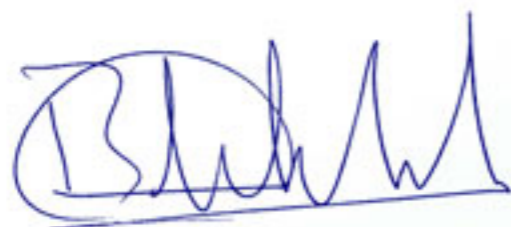
Issued to:

### **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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# EC CERTIFICATE

Number: 3812454CE01

1/2

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

### **Boston Scientific Corporation**

300 Boston Scientific Way  
Marlborough, MA 01752  
United States of America

For the product category(ies)

**Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

# 0344

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 above-mentioned manufacturer 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. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above-mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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# EC CERTIFICATE

Number: 3812454CE01

2/2

## Full Quality Assurance System

**Directive 93/42/EEC on Medical devices, Annex II excluding (4)**

(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

Manufacturer:

### **Boston Scientific Corporation**

300 Boston Scientific Way  
Marlborough, MA 01752  
United States of America

For the product category(ies)

**Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.**

Additionally, DEKRA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of Commission Regulation 722/2012 of 8 August 2012 concerning medical devices manufactured utilising tissue of animal origin. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory.

The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the 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  
Revised: 21 December 2018  
Reissued: 30 April 2020

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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# ADDENDUM

Belonging to certificate: 3812454CE01

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.


Issued to:

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

This certificate covers the following location(s):

| Location Code | Company name / address   | Location Code | Company name / address  |
|---------------|--|---------------|---|
| MAR2          | Boston Scientific Corporation<br>300 Boston Scientific Way<br>Marlborough, MA 01752<br>USA | CR2           | Boston Scientific Corporation<br>2546 First Street, Propark<br>El Coyol Alajuela<br>Costa Rica                                |
| COR           | Boston Scientific Limited<br>Business & Technology Park<br>Model Farm Rd<br>Cork, Ireland  | GAL           | Boston Scientific Limited<br>Ballybrit Business Park<br>Galway, Ireland   |
| COV           | Boston Scientific Corporation<br>8 Industrial Drive<br>Coventry, RI 02816<br>USA           | KER           | Boston Scientific<br>International BV<br>European Centre of Operations<br>Vestastraat 6, 6468 EX<br>Kerkrade, The Netherlands |

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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# ADDENDUM

Belonging to certificate: 3812454CE01

2/4

## CE MARKING OF CONFORMITY MEDICAL DEVICES

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

Issued to:

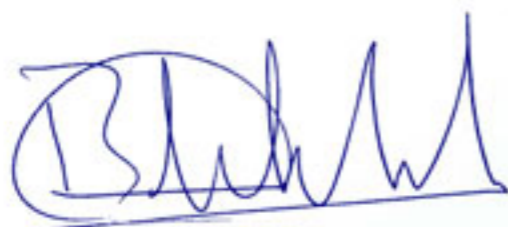
### **Boston Scientific Corporation**

300 Boston Scientific Way  
Marlborough, MA 01752  
United States of America

This certificate covers the following location(s): continued

| Location Code | Company name / address   | Location Code | Company name / address   |
|---------------|--|---------------|--|
| CR1           | Boston Scientific Corporation<br>302 Parkway<br>Global Park, Heredia<br>Costa Rica   | MAR           | Boston Scientific Corporation<br>100 Boston Scientific Way<br>Marlborough, MA 01752<br>USA |
| MG2           | Boston Scientific Corporation<br>Two Scimed Place<br>Maple Grove, MN 55311<br>USA    | SJ2           | Boston Scientific Corporation<br>150 Baytech Drive<br>San Jose, CA 95134<br>USA            |
| SP            | Boston Scientific Corporation<br>4100 Hamline Avenue N.<br>St. Paul, MN 55112<br>USA | SPE           | Boston Scientific Corporation<br>780 Brookside Drive<br>Spencer, IN 47460<br>USA           |

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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# ADDENDUM

Belonging to certificate: 3812454CE01

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

Issued to:

### **Boston Scientific Corporation**

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United States of America

This certificate covers the following location(s): continued

| Location Code | Company name / address   | Location Code | Company name / address   |
|---------------|--|---------------|--|
| QUI           | Boston Scientific Corporation<br>Marina Bay Customer<br>Fulfillment Center<br>500 Commander Shea Blvd<br>Quincy, MA 02171<br>USA   | ECU           | Symetis SA<br>Chemin de la Venoge 11<br>1024 Ecublens<br>Switzerland   |
| CHP           | ACURATE Indústria e Comércio<br>LTDA<br>Chapecó Site<br>Rua Apiuna, 520-D<br>Cristo Rei<br>Chapecó / SC – Brazil   | BHM           | ACURATE Indústria e Comércio LTD<br>BHM Site<br>(Belo Horizonte Site)<br>Avenida General David Sarnoff, 344<br>Lote 02 – Quadra 31A<br>Cidade Industrial<br>Contagem/MG – Brazil |
| PEN           | Boston Scientific Medical Device (Malaysia) Sdn. Bhd.<br>PMT 741, Persiaran Cassia Selatan 1<br>Taman Perindustrian Batu Kawan<br>14110 Bandar Cassia,<br>Pulau Pinang, Malaysia |               |  |

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.A. van Vugt  
Certification Manager

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# ADDENDUM

Belonging to certificate: 3812454CE01

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## CE MARKING OF CONFORMITY MEDICAL DEVICES

Medical Devices and Accessories for Minimally Invasive biliary, cardiovascular (including cardiovascular interventions), electrosurgical, endoscopic surgical, endoscopy, gastroenterology, gynaecology, nephrology, neurology (including neurovascular), peripheral (including peripheral interventions) and urology procedures.

Issued to:

### **Boston Scientific Corporation**

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

Initial date: 1 July 2014

Revision date: 1 June 2020

DEKRA Certification B.V.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping letters.

**B.T.M. Holtus**  
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing 'V' and 'V'.

**J.A. van Vugt**  
Certification Manager

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# SYNERGY™

Everolimus-Eluting Platinum Chromium Coronary Stent System

## Product Ordering Information

### Monorail™ Catheter

| ø<br>(mm) | Stent Length (mm) |                |                |                |                |                |                |                | Overexpansion<br>Capabilities |
|-----------|-------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|-------------------------------|
|           | 8                 | 12             | 16             | 20             | 24             | 28             | 32             | 38             |                               |
| 2.25      | H7493926008220    | H7493926012220 | H7493926016220 | H7493926020220 | H7493926024220 | H7493926028220 | H7493926032220 | H7493926038220 | 3.5                           |
| 2.50      | H7493926008250    | H7493926012250 | H7493926016250 | H7493926020250 | H7493926024250 | H7493926028250 | H7493926032250 | H7493926038250 | 3.5                           |
| 2.75      | H7493926008270    | H7493926012270 | H7493926016270 | H7493926020270 | H7493926024270 | H7493926028270 | H7493926032270 | H7493926038270 | 3.5                           |
| 3.00      | H7493926008300    | H7493926012300 | H7493926016300 | H7493926020300 | H7493926024300 | H7493926028300 | H7493926032300 | H7493926038300 | 4.25                          |
| 3.50      | H7493926008350    | H7493926012350 | H7493926016350 | H7493926020350 | H7493926024350 | H7493926028350 | H7493926032350 | H7493926038350 | 4.25                          |
| 4.00      | H7493926008400    | H7493926012400 | H7493926016400 | H7493926020400 | H7493926024400 | H7493926028400 | H7493926032400 | H7493926038400 | 5.75                          |
| 4.50      |                   | H7493926012450 | H7493926016450 | H7493926020450 | H7493926024450 | H7493926028450 | H7493926032450 |                | 5.75                          |
| 5.00      |                   | H7493926012500 | H7493926016500 | H7493926020500 | H7493926024500 | H7493926028500 | H7493926032500 |                | 5.75                          |

### Over-the-Wire Catheter

| ø<br>(mm) | Stent Length (mm) |                |                |                |                |                |                |                | Overexpansion<br>Capabilities |
|-----------|-------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|-------------------------------|
|           | 8                 | 12             | 16             | 20             | 24             | 28             | 32             | 38             |                               |
| 2.25      | H7493926108220    | H7493926112220 | H7493926116220 | H7493926120220 | H7493926124220 | H7493926128220 | H7493926132220 | H7493926138220 | 3.50                          |
| 2.50      | H7493926108250    | H7493926112250 | H7493926116250 | H7493926120250 | H7493926124250 | H7493926128250 | H7493926132250 | H7493926138250 | 3.50                          |
| 2.75      | H7493926108270    | H7493926112270 | H7493926116270 | H7493926120270 | H7493926124270 | H7493926128270 | H7493926132270 | H7493926138270 | 3.50                          |
| 3.00      | H7493926108300    | H7493926112300 | H7493926116300 | H7493926120300 | H7493926124300 | H7493926128300 | H7493926132300 | H7493926138300 | 4.25                          |
| 3.50      | H7493926108350    | H7493926112350 | H7493926116350 | H7493926120350 | H7493926124350 | H7493926128350 | H7493926132350 | H7493926138350 | 4.25                          |
| 4.00      | H7493926108400    | H7493926112400 | H7493926116400 | H7493926120400 | H7493926124400 | H7493926128400 | H7493926132400 | H7493926138400 | 5.75                          |