By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 635352**

Issued To: **Stryker Neurovascular**
47900 Bayside Parkway
Fremont
California
94538
USA

In respect of:

Design, Development, and Manufacture of Sterile Neurovascular Stents and Stent Delivery Systems, Neuro and Peripheral Vascular Embolization Coils, Coil Detachment Systems, Guidewires, Distal Access Catheters, Delivery Assist Catheters, Occlusion Balloon Catheters and Neuro, Peripheral and Coronary Vascular Microcatheters, Flow Diverters.

Those aspects of Annex II related to securing and maintaining sterility in the manufacture of Rotating Hemostatic Valves.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-06-01** Date: **2020-04-29** Expiry Date: **2024-05-26**

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Supplementary Information to CE 635352

Issued To:

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Number	Device Name	Intended purpose per IFU
Class III		
---	AXS Catalyst™ Distal Access Catheter	See CE 632309
---	AXS Offset™ Delivery Assist Catheter	See CE 632309
---	AXS Infinity LS Long Sheath	See CE 694301
---	Excelsior® 1018® Pre-shaped Microcatheters	See CE 635354
---	Excelsior® 1018® Reinforced Microcatheters	See CE 635354
---	Excelsior® SL-10® Pre-shaped Microcatheters	See CE 635354
---	Excelsior® SL-10® (Straight) Microcatheters	See CE 635354
---	Excelsior® XT-17™ Microcatheters	See CE 635354
---	Excelsior® XT-27® (Straight and Pre-shaped)	See CE 635354
---	Neuroform Atlas™ Stent System	See CE 632308
---	Neuroform EZ™ 3 Stent System	See CE 644526
---	Surpass Streamline™ Flow Diverter	See CE 644527
---	Surpass Evolve™ Flow Diverter System	See CE 700283
---	Synchro® Guidewires (-10 and -14)	See CE 637956
---	Synchro²® Guidewires	See CE 637954
---	Target™ Detachable Coils	See CE 635353
---	TransForm™ Occlusion Balloon Catheters	See CE 645956
---	Trenza™ Embolization Device	See CE 709778
---	Wingspan™ Stent System	See CE 644523

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Class IIa		
NBOG code: MD 1104	InZone Detachment System	---
Class Is		
NBOG code: MD 0102	Rotating Hemostatic Valve (RHV), Box of 5	---

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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 635352**
Date:	**2020-04-29**
Issued To:	**Stryker Neurovascular** **47900 Bayside Parkway** **Fremont** **California** **94538** **USA**

Subcontractor:	**Service(s) supplied**
Benchmark Electronics, Inc. Minnesota Division, Winona location 4065 Theurer Blvd. Winona Minnesota 55987 USA	**Manufacture**
Boston Scientific Corporation 302 Parkway Global Park Heredia Costa Rica	**Manufacture**
Boston Scientific Corporation Two Scimed Place Maple Grove Minnesota 55311 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Boston Scientific Limited Business and Technology Park Model Farm Road Cork Ireland	**Manufacture**
Isomedix Operations, Inc. North Facility 1880 Industrial Drive Libertyville Illinois 60048 USA	**Radiation (Gamma Sterilization)**
Isomedix Operations, Inc. 9120 South 150 East Sandy Utah 84070 USA	**Radiation (Gamma Sterilization)**

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**
Stryker European Operations B.V Herikerbergweg 110 Amsterdam 1101 CM The Netherlands	**EU Representative**
Stryker Neurovascular 4870 West 2100 South Salt Lake City Utah 84120 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Stryker Neurovascular Business & Technology Park Model Farm Road Cork Ireland	**Manufacture**
Synergy Health Ireland Ltd IDA Business & Technology Park Tullamore Co. Offaly Ireland	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
01 June 2015	8332563	Transfer from another Notified Body.
21 August 2015	8365050	Addition of Excelsior XT-17 Microcatheters to scope.
18 December 2015	8364858	Transfer from another Notified Body of the following devices: Synchro® 10 & 14 and Synchro2® Guidewires, Guglielmi Detachable Coils, Matrix^{2}® Detachable Coils, Wingspan® Stent System, Excelsior® family of Microcatheters (SL-10® Pre-Shaped, 1018® Reinforced, 1018® Pre-shaped, XT-27®), Tracker®-17 Microcatheters, FasTracker®10 & 18 and 18 MX Microcatheters and TransForm® Occlusion Balloon Catheters. Addition of signification subcontractors, Lake Region Medical, Pulse Systems, Sterigenics, and three STERIS Isomedix locations (Spartanburg, SC, Sandy, UT and Libertyville, IL).
10 February 2016	8457194	Consolidation of the scope of CE 632307 with CE 635352 and obsolescence of CE 632307. Correction of First Issued Date from December 18, 2015 to June 1, 2015. Addition of "Flow Diverters" from the scope CE 632307. Products include; Atlas Stent System, AXS catalyst Distal Access Catheter, Neuroform EZ and 3 Microdelivery Stent Systems, and Surpass Stream Line Flow Diverter. Addition of subcontractors and crucial suppliers from CE 632307, Secant Medical, NDC (Nitinol Devices & Components), and Heraeus Medical Components LLC. Addition of Sterigenics, Willowbrook, IL that was inadvertently omitted during the transfer.

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Date	Reference Number	Action
09 August 2016	8571667	Change of EU Representative from RAQA Manager Stryker France S.A.S. to Stryker European Operations B.V. Remove EU Representative information from all locations except the outer packaging product carton.
11 January 2017	8661493	Addition of Delivery Assist Catheters to the scope.
07 April 2017	8653826	Update of name of subcontractor NDC to Confluent Medical Technologies, Inc. Update the name Secant Medical, Inc. to The Secant Group, LLC, and update the address. Add the Trenton, Georgia, and Malaysia locations for Lake Region Medical to the certificate as significate subcontractors for manufacturing.
12 May 2017	8714504	Certificate renewal.
03 November 2017	8792659	Add Venusa de Mexico S. A. de C.V. to the certificate as a subcontractor for manufacturing. Add AdvanSource Biomaterials (ASB) to the certificate as a supplier of material crucial for the transform occlusion balloon catheter. Remove Steris Isomedix Services in Spartanburg, SC from the certificate, as this subcontractor is no longer used.
26 February 2018	8876758	Addition of Stryker (Salt Lake City, UT) for the activity of "Manufacture."

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Date	Reference Number	Action
20 March 2018	8855764	The name for the Salt Lake City site was corrected to Stryker Neurovascular.
25 January 2019	8366187	Traceable to NB 0086.

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Date	Reference Number	Action
06 March 2020	9769092	Addition of product supplementary information table. Removal of "Connecting Cables" from the scope of the certificate. Addition of subcontractors/suppliers: Boston Scientific Limited - Cork, Ireland; Boston Scientific Corporation – Heredia, Costa Rica; Boston Scientific Corporation - Maple Grove, Minnesota, USA. Addition of "Minnesota Division, Winona location" to address of "Benchmark Electronics, Inc.". Correction of "Synerg Health Ireland Ltd" to "Synergy Health Ireland Ltd" and removal of "Sragh". Rectification of subcontractor/supplier designation in line with ISO 13485 certificate: "STERIS Isomedix Services Inc." to "Isomedix Operations, Inc. North Facility" for the site in Libertyville, Illinois, 60048, USA, (MD 89745); "STERIS Isomedix Services Inc." to "Isomedix Operations, Inc." for the site in Sandy, Utah, 84070, USA (MD 89745). Removal of Stryker Neurovascular – West Valley City, USA. Removal of subcontractors/suppliers: AdvanSource Biomaterials (ASB) - USA; Confluent Medical Technologies Inc. - USA; Heraeus Medical Components LLC - USA; Lake Region Medical – Butlerland, Ireland; Lake Region Medical – Penang, Malaysia; Lake Region Medical - Trenton, Georgia, USA; Lake Regional Medical - Venusa de Mexico S.A. de C.V. - Juarez, Mexico; Pulse Systems - USA; Sterigenics - Willowbrook, Illinois, USA; The Secant Group, LLC - USA.
Current	9758755	Certificate renewal.