



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Certificate No. 2018-4-2011

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List
(Three Pages)

Name of Manufacturer, Address

Legal Manufacturer

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515
USA

Contract Manufacturer

Boston Scientific Corporation
47900 Bayside Parkway
Fremont, CA 94538-6515
USA

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the products(s) listed above.

Jennifer Medicus
Chief, Regulatory Policy and Systems Branch
Division of Risk Management Operations
Office of Compliance

**This certificate expires 24 months
from the date notarized.**

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 29 day of April month 2011 year.

CATHRYN N. MORRIS
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires January 4, 2013



Certificate to Foreign Government - Attachment (Page 1 of 3)

Name of Product(s)

Name of Manufacturer,
Address:

Neuroform 3™ Microdelivery Stent System

<u>Catalog #</u>	<u>UPN #</u>	<u>Description</u>
SNF32515	M003SNF325150	Neuroform 3 Microdelivery Stent System 2.5 x 15 mm
SNF32520	M003SNF325200	Neuroform 3 Microdelivery Stent System 2.5 x 20 mm
SNF33015	M003SNF330150	Neuroform 3 Microdelivery Stent System 3.0 x 15 mm
SNF33020	M003SNF330200	Neuroform 3 Microdelivery Stent System 3.0 x 20 mm
SNF33030	M003SNF330300	Neuroform 3 Microdelivery Stent System 3.0 x 30 mm
SNF33510	M003SNF335100	Neuroform 3 Microdelivery Stent System 3.5 x 10 mm
SNF33515	M003SNF335150	Neuroform 3 Microdelivery Stent System 3.5 x 15 mm
SNF33520	M003SNF335200	Neuroform 3 Microdelivery Stent System 3.5 x 20 mm
SNF33530	M003SNF335300	Neuroform 3 Microdelivery Stent System 3.5 x 30 mm
SNF34015	M003SNF340150	Neuroform 3 Microdelivery Stent System 4.0 x 15 mm
SNF34020	M003SNF340200	Neuroform 3 Microdelivery Stent System 4.0 x 20 mm
SNF34030	M003SNF340300	Neuroform 3 Microdelivery Stent System 4.0 x 30 mm
SNF34510	M003SNF345100	Neuroform 3 Microdelivery Stent System 4.5 x 10 mm
SNF34515	M003SNF345150	Neuroform 3 Microdelivery Stent System 4.5 x 15 mm
SNF34520	M003SNF345200	Neuroform 3 Microdelivery Stent System 4.5 x 20 mm
SNF34530	M003SNF345300	Neuroform 3 Microdelivery Stent System 4.5 x 30 mm

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Certificate to Foreign Government - Attachment (Page 2 of 3)

Name of Product(s)

Name of Manufacturer,
Address:

Neuroform™ Stent Accessories

<u>Catalog #</u>	<u>UPN #</u>	<u>Description</u>
SNF3STA	M003SNF3STA0	Neuroform Stent Stabilizer Catheter

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BSC Detachable Coil Power Supply

<u>Catalog #</u>	<u>UPN #</u>	<u>Description</u>
451007-4	M00345100740	BSC Detachable Coil Power Supply

BSC Detachable Coil Connecting Cables

<u>Catalog #</u>	<u>UPN #</u>	<u>Description</u>
451102-4	M00345110240	BSC Detachable Coil Connecting Cables

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Name of Product(s)

Name of Manufacturer,
Address:

Wingspan™ Stent System

<u>Catalog #</u>	<u>UPN #</u>	<u>Description</u>
WS025009	M003WS0250090	Wingspan Stent System 2.5 x 9 mm
WS025015	M003WS0250150	Wingspan Stent System 2.5 x 15 mm
WS025020	M003WS0250200	Wingspan Stent System 2.5 x 20 mm
WS030009	M003WS0300090	Wingspan Stent System 3.0 x 9 mm
WS030015	M003WS0300150	Wingspan Stent System 3.0 x 15 mm
WS030020	M003WS0300200	Wingspan Stent System 3.0 x 20 mm
WS035009	M003WS0350090	Wingspan Stent System 3.5 x 9 mm
WS035015	M003WS0350150	Wingspan Stent System 3.5 x 15 mm
WS035020	M003WS0350200	Wingspan Stent System 3.5 x 20 mm
WS040009	M003WS0400090	Wingspan Stent System 4.0 x 9 mm
WS040015	M003WS0400150	Wingspan Stent System 4.0 x 15 mm
WS040020	M003WS0400200	Wingspan Stent System 4.0 x 20 mm
WS045009	M003WS0450090	Wingspan Stent System 4.5 x 9 mm
WS045015	M003WS0450150	Wingspan Stent System 4.5 x 15 mm
WS045020	M003WS0450200	Wingspan Stent System 4.5 x 20 mm

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End of Product List

