

SGS

Certificate US13/82824

The management system of

InSitu Technologies, Inc.

539 Phalen Boulevard,
St. Paul, MN, 55130, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

Design, Development, Manufacture and Distribution of sterile coronary and peripheral stent and delivery systems. Distribution of minimally Invasive Intravascular Medical Devices including: Coronary and Peripheral Covered Stents, Coronary and Peripheral Bare Metal Stents, and PTCA and PTA Balloon Dilatation Catheters; and Distribution of Angioplasty accessories including Guide Wires, Hemostatic Patch systems, Inflation Devices, Introducer Sheaths and Angioplasty Kits including Hemostatic Valves, Needles and Torque Devices.

This certificate is valid from 31 March 2019 until 31 March 2022 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 4. Certified since 2 May 2013

Authorised by



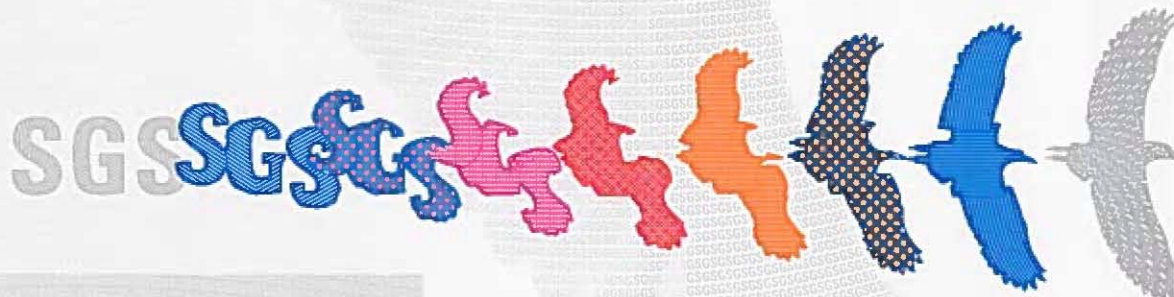
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SGS 13485-2 1114

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Certificate No. 15496-9-2017

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/Distributor, Address

Name of Manufacturer
INSITU TECHNOLOGIES, INC.
539 Phalen Blvd
Saint Paul, MN USA 55130

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.

Robin W. Newman MSN EdD CPNP
Director
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 29, 2017 to September 28, 2019.





**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 15496-9-2017

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

Name of Manufacturer

INSITU TECHNOLOGIES, INC.

539 Phalen Blvd

Saint Paul, MN USA 55130

Name of Product(s)

411210 Arriva PTCA Coronary Balloon Catheter 1.25 x 10
411215 Arriva PTCA Coronary Balloon Catheter 1.25 x 15
411220 Arriva PTCA Coronary Balloon Catheter 1.25 x 20
411510 Arriva PTCA Coronary Balloon Catheter 1.5 x 10
411515 Arriva PTCA Coronary Balloon Catheter 1.5 x 15
411520 Arriva PTCA Coronary Balloon Catheter 1.5 x 20
411530 Arriva PTCA Coronary Balloon Catheter 1.5 x 30
412010 Arriva PTCA Coronary Balloon Catheter 2.0 x 10
412015 Arriva PTCA Coronary Balloon Catheter 2.0 x 15
412020 Arriva PTCA Coronary Balloon Catheter 2.0 x 20
412030 Arriva PTCA Coronary Balloon Catheter 2.0 x 30
4122510 Arriva PTCA Coronary Balloon Catheter 2.25 x 10
4122515 Arriva PTCA Coronary Balloon Catheter 2.25 x 15
4122520 Arriva PTCA Coronary Balloon Catheter 2.25 x 20
4122530 Arriva PTCA Coronary Balloon Catheter 2.25 x 30
412510 Arriva PTCA Coronary Balloon Catheter 2.5 x 10
412515 Arriva PTCA Coronary Balloon Catheter 2.5 x 15
412520 Arriva PTCA Coronary Balloon Catheter 2.5 x 20
412530 Arriva PTCA Coronary Balloon Catheter 2.5 x 30
413010 Arriva PTCA Coronary Balloon Catheter 3.0 x 10
413015 Arriva PTCA Coronary Balloon Catheter 3.0 x 15
413020 Arriva PTCA Coronary Balloon Catheter 3.0 x 20
413025 Arriva PTCA Coronary Balloon Catheter 3.0 x 25
413030 Arriva PTCA Coronary Balloon Catheter 3.0 x 30
413035 Arriva PTCA Coronary Balloon Catheter 3.0 x 35
4132510 Arriva PTCA Coronary Balloon Catheter 3.25 x 10
4132515 Arriva PTCA Coronary Balloon Catheter 3.25 x 15
4132520 Arriva PTCA Coronary Balloon Catheter 3.25 x 20
4132530 Arriva PTCA Coronary Balloon Catheter 3.25 x 30
413510 Arriva PTCA Coronary Balloon Catheter 3.5 x 10
413515 Arriva PTCA Coronary Balloon Catheter 3.5 x 15
413520 Arriva PTCA Coronary Balloon Catheter 3.5 x 20
413530 Arriva PTCA Coronary Balloon Catheter 3.5 x 30
413535 Arriva PTCA Coronary Balloon Catheter 3.5 x 35
4137510 Arriva PTCA Coronary Balloon Catheter 3.75 x 10
4137515 Arriva PTCA Coronary Balloon Catheter 3.75 x 15
4137520 Arriva PTCA Coronary Balloon Catheter 3.75 x 20
4137530 Arriva PTCA Coronary Balloon Catheter 3.75 x 30
414010 Arriva PTCA Coronary Balloon Catheter 4.0 x 10
414015 Arriva PTCA Coronary Balloon Catheter 4.0 x 15
414020 Arriva PTCA Coronary Balloon Catheter 4.0 x 20
414030 Arriva PTCA Coronary Balloon Catheter 4.0 x 30
414040 Arriva PTCA Coronary Balloon Catheter 4.0 x 40
414510 Arriva PTCA Coronary Balloon Catheter 4.5 x 10
414515 Arriva PTCA Coronary Balloon Catheter 4.5 x 15
414520 Arriva PTCA Coronary Balloon Catheter 4.5 x 20
414530 Arriva PTCA Coronary Balloon Catheter 4.5 x 30
415020 Arriva PTCA Coronary Balloon Catheter 5.0 x 20
415030 Arriva PTCA Coronary Balloon Catheter 5.0 x 30
415040 Arriva PTCA Coronary Balloon Catheter 5.0 x 40
416020 Arriva PTCA Coronary Balloon Catheter 6.0 x 20
416030 Arriva PTCA Coronary Balloon Catheter 6.0 x 30





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416040 Arriva PTCA Coronary Balloon Catheter 6.0 x 40
417020 Arriva PTCA Coronary Balloon Catheter 7.0 x 20
417025 Arriva PTCA Coronary Balloon Catheter 7.0 x 25
417030 Arriva PTCA Coronary Balloon Catheter 7.0 x 30
417040 Arriva PTCA Coronary Balloon Catheter 7.0 x 40
417060 Arriva PTCA Coronary Balloon Catheter 7.0 x 60
442010 Arriva NC Non-Compliant PTCA Balloon Catheter 2.0 x 10
442015 Arriva NC Non-Compliant PTCA Balloon Catheter 2.0 x 15
442020 Arriva NC Non-Compliant PTCA Balloon Catheter 2.0 x 20
442030 Arriva NC Non-Compliant PTCA Balloon Catheter 2.0 x 30
442510 Arriva NC Non-Compliant PTCA Balloon Catheter 2.5 x 10
442515 Arriva NC Non-Compliant PTCA Balloon Catheter 2.5 x 15
442520 Arriva NC Non-Compliant PTCA Balloon Catheter 2.5 x 20
442530 Arriva NC Non-Compliant PTCA Balloon Catheter 2.5 x 30
443010 Arriva NC Non-Compliant PTCA Balloon Catheter 3.0 x 10
443015 Arriva NC Non-Compliant PTCA Balloon Catheter 3.0 x 15
443020 Arriva NC Non-Compliant PTCA Balloon Catheter 3.0 x 20
443030 Arriva NC Non-Compliant PTCA Balloon Catheter 3.0 x 30
443510 Arriva NC Non-Compliant PTCA Balloon Catheter 3.5 x 10
443515 Arriva NC Non-Compliant PTCA Balloon Catheter 3.5 x 15
443520 Arriva NC Non-Compliant PTCA Balloon Catheter 3.5 x 20
443530 Arriva NC Non-Compliant PTCA Balloon Catheter 3.5 x 30
444010 Arriva NC Non-Compliant PTCA Balloon Catheter 4.0 x 10
444015 Arriva NC Non-Compliant PTCA Balloon Catheter 4.0 x 15
444020 Arriva NC Non-Compliant PTCA Balloon Catheter 4.0 x 20
444030 Arriva NC Non-Compliant PTCA Balloon Catheter 4.0 x 30
444510 Arriva NC Non-Compliant PTCA Balloon Catheter 4.5 x 10
444515 Arriva NC Non-Compliant PTCA Balloon Catheter 4.5 x 15
444520 Arriva NC Non-Compliant PTCA Balloon Catheter 4.5 x 20
444530 Arriva NC Non-Compliant PTCA Balloon Catheter 4.5 x 30
776020-135 Hercules PTA Peripheral Balloon Catheter 6.0 x 20 WL 135cm
776030-135 Hercules PTA Peripheral Balloon Catheter 6.0 x 30 WL 135cm
776040-135 Hercules PTA Peripheral Balloon Catheter 6.0 x 40 WL 135cm
776060-135 Hercules PTA Peripheral Balloon Catheter 6.0 x 60 WL 135cm
776080-135 Hercules PTA Peripheral Balloon Catheter 6.0 x 80 WL 135cm
777020-135 Hercules PTA Peripheral Balloon Catheter 7.0 x 20 WL 135cm
777030-135 Hercules PTA Peripheral Balloon Catheter 7.0 x 30 WL 135cm
777040-135 Hercules PTA Peripheral Balloon Catheter 7.0 x 40 WL 135cm
777060-135 Hercules PTA Peripheral Balloon Catheter 7.0 x 60 WL 135cm
777080-135 Hercules PTA Peripheral Balloon Catheter 7.0 x 80 WL 135cm
778020-135 Hercules PTA Peripheral Balloon Catheter 8.0 x 20 WL 135cm
778030-135 Hercules PTA Peripheral Balloon Catheter 8.0 x 30 WL 135cm
778040-135 Hercules PTA Peripheral Balloon Catheter 8.0 x 40 WL 135cm
778060-135 Hercules PTA Peripheral Balloon Catheter 8.0 x 60 WL 135cm
778080-135 Hercules PTA Peripheral Balloon Catheter 8.0 x 80 WL 135cm
779020-135 Hercules PTA Peripheral Balloon Catheter 9.0 x 20 WL 135cm
779030-135 Hercules PTA Peripheral Balloon Catheter 9.0 x 30 WL 135cm
779040-135 Hercules PTA Peripheral Balloon Catheter 9.0 x 40 WL 135cm
779060-135 Hercules PTA Peripheral Balloon Catheter 9.0 x 60 WL 135cm
779080-135 Hercules PTA Peripheral Balloon Catheter 9.0 x 80 WL 135cm
7710020-135 Hercules PTA Peripheral Balloon Catheter 10.0 x 20 WL 135cm
7710030-135 Hercules PTA Peripheral Balloon Catheter 10.0 x 30 WL 135cm
7710040-135 Hercules PTA Peripheral Balloon Catheter 10.0 x 40 WL 135cm
7710060-135 Hercules PTA Peripheral Balloon Catheter 10.0 x 60 WL 135cm
7710080-135 Hercules PTA Peripheral Balloon Catheter 10.0 x 80 WL 135cm
7712020-135 Hercules PTA Peripheral Balloon Catheter 12.0 x 20 WL 135cm
7712030-135 Hercules PTA Peripheral Balloon Catheter 12.0 x 30 WL 135cm





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See Attached List

Name of Manufacturer/Distributor, Address

Name of Manufacturer
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Certificate of Exportability Section 802 - Name of Product(s) Attachment Page 1 of 9

Manufacturing Location

INSITU TECHNOLOGIES, INC.
 539 Phalen Blvd
 Saint Paul, MN USA 55130

Name of Product(s)

7622510 Celosia Covered Coronary Stent	2.25 x 10
7622513 Celosia Covered Coronary Stent	2.25 x 13
7622516 Celosia Covered Coronary Stent	2.25 x 16
7622519 Celosia Covered Coronary Stent	2.25 x 19
7622523 Celosia Covered Coronary Stent	2.25 x 23
7622526 Celosia Covered Coronary Stent	2.25 x 26
7622530 Celosia Covered Coronary Stent	2.25 x 30
762510 Celosia Covered Coronary Stent	2.5 x 10
762513 Celosia Covered Coronary Stent	2.5 x 13
762516 Celosia Covered Coronary Stent	2.5 x 16
762519 Celosia Covered Coronary Stent	2.5 x 19
762523 Celosia Covered Coronary Stent	2.5 x 23
762526 Celosia Covered Coronary Stent	2.5 x 26
762530 Celosia Covered Coronary Stent	2.5 x 30
762534 Celosia Covered Coronary Stent	2.5 x 34
762538 Celosia Covered Coronary Stent	2.5 x 38
7627510 Celosia Covered Coronary Stent	2.75 x 10
7627513 Celosia Covered Coronary Stent	2.75 x 13
7627516 Celosia Covered Coronary Stent	2.75 x 16
7627519 Celosia Covered Coronary Stent	2.75 x 19
7627523 Celosia Covered Coronary Stent	2.75 x 23
7627526 Celosia Covered Coronary Stent	2.75 x 26
7627530 Celosia Covered Coronary Stent	2.75 x 30
7627534 Celosia Covered Coronary Stent	2.75 x 34
7627538 Celosia Covered Coronary Stent	2.75 x 38
763010 Celosia Covered Coronary Stent	3.0 x 10
763013 Celosia Covered Coronary Stent	3.0 x 13
763016 Celosia Covered Coronary Stent	3.0 x 16
763019 Celosia Covered Coronary Stent	3.0 x 19
763023 Celosia Covered Coronary Stent	3.0 x 23
763026 Celosia Covered Coronary Stent	3.0 x 26
763030 Celosia Covered Coronary Stent	3.0 x 30
763034 Celosia Covered Coronary Stent	3.0 x 34
763038 Celosia Covered Coronary Stent	3.0 x 38
763510 Celosia Covered Coronary Stent	3.5 x 10
763513 Celosia Covered Coronary Stent	3.5 x 13
763516 Celosia Covered Coronary Stent	3.5 x 16
763519 Celosia Covered Coronary Stent	3.5 x 19
763523 Celosia Covered Coronary Stent	3.5 x 23
763526 Celosia Covered Coronary Stent	3.5 x 26
763530 Celosia Covered Coronary Stent	3.5 x 30
763534 Celosia Covered Coronary Stent	3.5 x 34
763538 Celosia Covered Coronary Stent	3.5 x 38
764010 Celosia Covered Coronary Stent	4.0 x 10
764013 Celosia Covered Coronary Stent	4.0 x 13
764016 Celosia Covered Coronary Stent	4.0 x 16
764019 Celosia Covered Coronary Stent	4.0 x 19
764023 Celosia Covered Coronary Stent	4.0 x 23
764026 Celosia Covered Coronary Stent	4.0 x 26
764030 Celosia Covered Coronary Stent	4.0 x 30





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- 764034 Celosia Covered Coronary Stent 4.0 x 34
- 764038 Celosia Covered Coronary Stent 4.0 x 38
- 764515 Celosia Covered Coronary Stent 4.5 x 15
- 764519 Celosia Covered Coronary Stent 4.5 x 19
- 764523 Celosia Covered Coronary Stent 4.5 x 23
- 764526 Celosia Covered Coronary Stent 4.5 x 26
- 764530 Celosia Covered Coronary Stent 4.5 x 30
- 764534 Celosia Covered Coronary Stent 4.5 x 34
- 764538 Celosia Covered Coronary Stent 4.5 x 38
- 765015 Celosia Covered Coronary Stent 5.0 x 15
- 765018 Celosia Covered Coronary Stent 5.0 x 18
- 765024 Celosia Covered Coronary Stent 5.0 x 24
- 765030 Celosia Covered Coronary Stent 5.0 x 30
- 765035 Celosia Covered Coronary Stent 5.0 x 35
- 765038 Celosia Covered Coronary Stent 5.0 x 38
- 766015 Celosia Covered Coronary Stent 6.0 x 15
- 766030 Celosia Covered Coronary Stent 6.0 x 30
- 766033 Celosia Covered Coronary Stent 6.0 x 33
- 766035 Celosia Covered Coronary Stent 6.0 x 35
- 767014 Celosia Covered Coronary Stent 7.0 x 14
- 707014 Celosia Covered Coronary Stent 7.0 x 17
- 707023 Celosia Covered Coronary Stent 7.0 x 23
- 707028 Celosia Covered Coronary Stent 7.0 x 28
- 707033 Celosia Covered Coronary Stent 7.0 x 33
- 7022510 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.25 x 10
- 7022513 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.25 x 13
- 7022516 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.25 x 16
- 7022519 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.25 x 19
- 7022523 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.25 x 23
- 7022526 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.25 x 26
- 7022530 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.25 x 30
- 702510 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 10
- 702513 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 13
- 702516 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 16
- 702519 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 19
- 702523 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 23
- 702526 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 26
- 702530 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 30
- 702534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 34
- 702544 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 44
- 702548 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 48
- 702538 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.5 x 38
- 7027510 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 10
- 7027513 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 13
- 7027516 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 16
- 7027519 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 19
- 7027523 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 23
- 7027526 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 26
- 7027530 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 30
- 7027534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 34
- 7027538 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 38
- 703544 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 44
- 703548 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 2.75 x 48
- 703010 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.0 x 10
- 703013 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.0 x 13
- 703016 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.0 x 16
- 703019 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.0 x 19
- 703019 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.0 x 23





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703026 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.0 x 26
703026 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.0 x 30
703026 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.0 x 34
703026 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.0 x 38
703534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 10
703534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 13
703534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 16
703534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 19
703534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 23
703534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 26
703534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 30
703534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 34
703538 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 38
703544 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 44
703548 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 3.5 x 48
704010 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.0 x 10
704013 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.0 x 13
704016 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.0 x 16
704019 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.0 x 19
704023 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.0 x 23
704026 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.0 x 26
704030 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.0 x 30
704034 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.0 x 34
704038 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.0 x 38
704515 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.5 x 15
704519 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.5 x 19
704523 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.5 x 23
704526 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.5 x 26
704530 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.5 x 30
704534 Direct-Stent SIRO Sirolimus Eluting Coronary Stent 4.5 x 34
6222510 Direct-Stent CC Coronary Stent 2.25 x 10
6222513 Direct-Stent CC Coronary Stent 2.25 x 13
6222516 Direct-Stent CC Coronary Stent 2.25 x 16
6222519 Direct-Stent CC Coronary Stent 2.25 x 19
6222523 Direct-Stent CC Coronary Stent 2.25 x 23
6222526 Direct-Stent CC Coronary Stent 2.25 x 26
6222530 Direct-Stent CC Coronary Stent 2.25 x 30
622510 Direct-Stent CC Coronary Stent 2.5 x 10
622513 Direct-Stent CC Coronary Stent 2.5 x 13
622516 Direct-Stent CC Coronary Stent 2.5 x 16
622519 Direct-Stent CC Coronary Stent 2.5 x 19
622523 Direct-Stent CC Coronary Stent 2.5 x 23
622526 Direct-Stent CC Coronary Stent 2.5 x 26
622530 Direct-Stent CC Coronary Stent 2.5 x 30
622534 Direct-Stent CC Coronary Stent 2.5 x 34
622538 Direct-Stent CC Coronary Stent 2.5 x 38
6227510 Direct-Stent CC Coronary Stent 2.75 x 10
6227513 Direct-Stent CC Coronary Stent 2.75 x 13
6227516 Direct-Stent CC Coronary Stent 2.75 x 16
6227519 Direct-Stent CC Coronary Stent 2.75 x 19
6227523 Direct-Stent CC Coronary Stent 2.75 x 23
6227526 Direct-Stent CC Coronary Stent 2.75 x 26
6227530 Direct-Stent CC Coronary Stent 2.75 x 30
6227534 Direct-Stent CC Coronary Stent 2.75 x 34
6227538 Direct-Stent CC Coronary Stent 2.75 x 38
623010 Direct-Stent CC Coronary Stent 3.0 x 10
623013 Direct-Stent CC Coronary Stent 3.0 x 13
623016 Direct-Stent CC Coronary Stent 3.0 x 16





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623019 Direct-Stent CC Coronary Stent 3.0 x 19
623023 Direct-Stent CC Coronary Stent 3.0 x 23
623026 Direct-Stent CC Coronary Stent 3.0 x 26
623030 Direct-Stent CC Coronary Stent 3.0 x 30
623034 Direct-Stent CC Coronary Stent 3.0 x 34
623038 Direct-Stent CC Coronary Stent 3.0 x 38
623510 Direct-Stent CC Coronary Stent 3.5 x 10
623513 Direct-Stent CC Coronary Stent 3.5 x 13
623516 Direct-Stent CC Coronary Stent 3.5 x 16
623519 Direct-Stent CC Coronary Stent 3.5 x 19
623523 Direct-Stent CC Coronary Stent 3.5 x 23
623526 Direct-Stent CC Coronary Stent 3.5 x 26
623530 Direct-Stent CC Coronary Stent 3.5 x 30
623534 Direct-Stent CC Coronary Stent 3.5 x 34
623538 Direct-Stent CC Coronary Stent 3.5 x 38
624010 Direct-Stent CC Coronary Stent 4.0 x 10
624013 Direct-Stent CC Coronary Stent 4.0 x 13
624016 Direct-Stent CC Coronary Stent 4.0 x 16
624019 Direct-Stent CC Coronary Stent 4.0 x 19
624023 Direct-Stent CC Coronary Stent 4.0 x 23
624026 Direct-Stent CC Coronary Stent 4.0 x 26
624030 Direct-Stent CC Coronary Stent 4.0 x 30
624034 Direct-Stent CC Coronary Stent 4.0 x 34
624038 Direct-Stent CC Coronary Stent 4.0 x 38
684515 Diamondback Biliary Stent 4.5 x 15
684519 Diamondback Biliary Stent 4.5 x 19
684523 Diamondback Biliary Stent 4.5 x 23
684526 Diamondback Biliary Stent 4.5 x 26
684530 Diamondback Biliary Stent 4.5 x 30
684534 Diamondback Biliary Stent 4.5 x 34
684538 Diamondback Biliary Stent 4.5 x 38
685015 Diamondback Biliary Stent 5.0 x 15
685018 Diamondback Biliary Stent 5.0 x 18
685024 Diamondback Biliary Stent 5.0 x 24
685030 Diamondback Biliary Stent 5.0 x 30
685035 Diamondback Biliary Stent 5.0 x 35
685038 Diamondback Biliary Stent 5.0 x 38
686015 Diamondback Biliary Stent 6.0 x 15
686018 Diamondback Biliary Stent 6.0 x 18
686024 Diamondback Biliary Stent 6.0 x 24
686030 Diamondback Biliary Stent 6.0 x 30
686033 Diamondback Biliary Stent 6.0 x 33
687017 Diamondback Biliary Stent 7.0 x 17
687023 Diamondback Biliary Stent 7.0 x 23
687028 Diamondback Biliary Stent 7.0 x 28
687030 Diamondback Biliary Stent 7.0 x 30
687033 Diamondback Biliary Stent 7.0 x 33
756015-135 Silene Peripheral Covered Stent 6.0 x 15
756025-135 Silene Peripheral Covered Stent 6.0 x 25
756035-135 Silene Peripheral Covered Stent 6.0 x 35
756050-135 Silene Peripheral Covered Stent 6.0 x 50
756070-135 Silene Peripheral Covered Stent 6.0 x 70
757015-135 Silene Peripheral Covered Stent 7.0 x 15
757025-135 Silene Peripheral Covered Stent 7.0 x 25
757035-135 Silene Peripheral Covered Stent 7.0 x 35
757050-135 Silene Peripheral Covered Stent 7.0 x 50
757070-135 Silene Peripheral Covered Stent 7.0 x 70
758015-135 Silene Peripheral Covered Stent 8.0 x 15





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758024-135 Silene Peripheral Covered Stent 8.0 x 24
758032-135 Silene Peripheral Covered Stent 8.0 x 32
758050-135 Silene Peripheral Covered Stent 8.0 x 50
758070-135 Silene Peripheral Covered Stent 8.0 x 70
759015-135 Silene Peripheral Covered Stent 9.0 x 15
759024-135 Silene Peripheral Covered Stent 9.0 x 24
759032-135 Silene Peripheral Covered Stent 9.0 x 32
759050-135 Silene Peripheral Covered Stent 9.0 x 50
759070-135 Silene Peripheral Covered Stent 9.0 x 70
7510015-135 Silene Peripheral Covered Stent 10.0 x 15
7510023-135 Silene Peripheral Covered Stent 10.0 x 23
7510031-135 Silene Peripheral Covered Stent 10.0 x 31
7510048-135 Silene Peripheral Covered Stent 10.0 x 48
7510065-135 Silene Peripheral Covered Stent 10.0 x 65
7512014-120 Silene Peripheral Covered Stent 12.0 x 14
7512023-120 Silene Peripheral Covered Stent 12.0 x 23
7512031-120 Silene Peripheral Covered Stent 12.0 x 31
7512047-120 Silene Peripheral Covered Stent 12.0 x 47
7512065-120 Silene Peripheral Covered Stent 12.0 x 65
7514030-120 Silene Peripheral Covered Stent 14.0 x 30
7514045-120 Silene Peripheral Covered Stent 14.0 x 45
7514058-120 Silene Peripheral Covered Stent 14.0 x 58
786015-135 Diamondback Peripheral Stent OTW 6.0 x 15
786025-135 Diamondback Peripheral Stent OTW 6.0 x 25
786035-135 Diamondback Peripheral Stent OTW 6.0 x 35
786050-135 Diamondback Peripheral Stent OTW 6.0 x 50
786070-135 Diamondback Peripheral Stent OTW 6.0 x 70
787015-135 Diamondback Peripheral Stent OTW 7.0 x 15
787025-135 Diamondback Peripheral Stent OTW 7.0 x 25
787035-135 Diamondback Peripheral Stent OTW 7.0 x 35
787050-135 Diamondback Peripheral Stent OTW 7.0 x 50
787070-135 Diamondback Peripheral Stent OTW 7.0 x 70
788015-135 Diamondback Peripheral Stent OTW 8.0 x 15
788024-135 Diamondback Peripheral Stent OTW 8.0 x 24
788032-135 Diamondback Peripheral Stent OTW 8.0 x 32
788050-135 Diamondback Peripheral Stent OTW 8.0 x 50
788070-135 Diamondback Peripheral Stent OTW 8.0 x 70
789015-135 Diamondback Peripheral Stent OTW 9.0 x 15
789024-135 Diamondback Peripheral Stent OTW 9.0 x 24
789032-135 Diamondback Peripheral Stent OTW 9.0 x 32
789050-135 Diamondback Peripheral Stent OTW 9.0 x 50
789070-135 Diamondback Peripheral Stent OTW 9.0 x 70
7810015-135 Diamondback Peripheral Stent OTW 10.0 x 15
7810023-135 Diamondback Peripheral Stent OTW 10.0 x 23
7810031-135 Diamondback Peripheral Stent OTW 10.0 x 31
7810048-135 Diamondback Peripheral Stent OTW 10.0 x 48
7810065-135 Diamondback Peripheral Stent OTW 10.0 x 65
7812014-120 Diamondback Peripheral Stent OTW 12.0 x 14
7812023-120 Diamondback Peripheral Stent OTW 12.0 x 23
7812031-120 Diamondback Peripheral Stent OTW 12.0 x 31
7812047-120 Diamondback Peripheral Stent OTW 12.0 x 47
7812065-120 Diamondback Peripheral Stent OTW 12.0 x 65
7814030-120 Diamondback Peripheral Stent OTW 14.0 x 30
7814045-120 Diamondback Peripheral Stent OTW 14.0 x 45
7814058-120 Diamondback Peripheral Stent OTW 14.0 x 58
834020-135 LuMend Nitinol Stent Graft 4.0 x 20
834030-135 LuMend Nitinol Stent Graft 4.0 x 30
834040-135 LuMend Nitinol Stent Graft 4.0 x 40





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834060-135 LuMend Nitinol Stent Graft 4.0 x 60
835020-135 LuMend Nitinol Stent Graft 5.0 x 20
835030-135 LuMend Nitinol Stent Graft 5.0 x 30
835040-135 LuMend Nitinol Stent Graft 5.0 x 40
835060-135 LuMend Nitinol Stent Graft 5.0 x 60
836020-135 LuMend Nitinol Stent Graft 6.0 x 20
836040-135 LuMend Nitinol Stent Graft 6.0 x 40
836060-135 LuMend Nitinol Stent Graft 6.0 x 60
836080-135 LuMend Nitinol Stent Graft 6.0 x 80
8360100-135 LuMend Nitinol Stent Graft 6.0 x 100
837020-135 LuMend Nitinol Stent Graft 7.0 x 20
837030-135 LuMend Nitinol Stent Graft 7.0 x 30
837040-135 LuMend Nitinol Stent Graft 7.0 x 40
837060-135 LuMend Nitinol Stent Graft 7.0 x 60
837080-135 LuMend Nitinol Stent Graft 7.0 x 80
8370100-135 LuMend Nitinol Stent Graft 7.0 x 100
838020-135 LuMend Nitinol Stent Graft 8.0 x 20
838030-135 LuMend Nitinol Stent Graft 8.0 x 30
838040-135 LuMend Nitinol Stent Graft 8.0 x 40
838080-135 LuMend Nitinol Stent Graft 8.0 x 80
8380100-135 LuMend Nitinol Stent Graft 8.0 x 100
839020-135 LuMend Nitinol Stent Graft 9.0 x 20
839030-135 LuMend Nitinol Stent Graft 9.0 x 30
839040-135 LuMend Nitinol Stent Graft 9.0 x 40
839060-135 LuMend Nitinol Stent Graft 9.0 x 60
839080-135 LuMend Nitinol Stent Graft 9.0 x 80
8390100-135 LuMend Nitinol Stent Graft 9.0 x 100
8310020-135 LuMend Nitinol Stent Graft 10.0 x 20
8310030-135 LuMend Nitinol Stent Graft 10.0 x 30
8310040-135 LuMend Nitinol Stent Graft 10.0 x 40
8310060-135 LuMend Nitinol Stent Graft 10.0 x 60
8310080-135 LuMend Nitinol Stent Graft 10.0 x 80
83100100-135 LuMend Nitinol Stent Graft 10.0 x 100
8312020-135 LuMend Nitinol Stent Graft 12.0 x 20
8312030-135 LuMend Nitinol Stent Graft 12.0 x 30
8312040-135 LuMend Nitinol Stent Graft 12.0 x 40
8312060-135 LuMend Nitinol Stent Graft 12.0 x 60
8312080-135 LuMend Nitinol Stent Graft 12.0 x 80
83120120-135 LuMend Nitinol Stent Graft 12.0 x 120
411210 Arriva PTCA Coronary Balloon Catheter 1.25 x 10
411215 Arriva PTCA Coronary Balloon Catheter 1.25 x 15
411220 Arriva PTCA Coronary Balloon Catheter 1.25 x 20
411510 Arriva PTCA Coronary Balloon Catheter 1.5 x 10
411515 Arriva PTCA Coronary Balloon Catheter 1.5 x 15
411520 Arriva PTCA Coronary Balloon Catheter 1.5 x 20
411530 Arriva PTCA Coronary Balloon Catheter 1.5 x 30
412010 Arriva PTCA Coronary Balloon Catheter 2.0 x 10
412015 Arriva PTCA Coronary Balloon Catheter 2.0 x 15
412020 Arriva PTCA Coronary Balloon Catheter 2.0 x 20
412030 Arriva PTCA Coronary Balloon Catheter 2.0 x 30
4122510 Arriva PTCA Coronary Balloon Catheter 2.25 x 10
4122515 Arriva PTCA Coronary Balloon Catheter 2.25 x 15
4122520 Arriva PTCA Coronary Balloon Catheter 2.25 x 20
4122530 Arriva PTCA Coronary Balloon Catheter 2.25 x 30
412510 Arriva PTCA Coronary Balloon Catheter 2.5 x 10
412515 Arriva PTCA Coronary Balloon Catheter 2.5 x 15
412520 Arriva PTCA Coronary Balloon Catheter 2.5 x 20
412530 Arriva PTCA Coronary Balloon Catheter 2.5 x 30





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413010 Arriva PTCA Coronary Balloon Catheter 3.0 x 10
413015 Arriva PTCA Coronary Balloon Catheter 3.0 x 15
413020 Arriva PTCA Coronary Balloon Catheter 3.0 x 20
413025 Arriva PTCA Coronary Balloon Catheter 3.0 x 25
413030 Arriva PTCA Coronary Balloon Catheter 3.0 x 30
413035 Arriva PTCA Coronary Balloon Catheter 3.0 x 35
4132510 Arriva PTCA Coronary Balloon Catheter 3.25 x 10
4132515 Arriva PTCA Coronary Balloon Catheter 3.25 x 15
4132520 Arriva PTCA Coronary Balloon Catheter 3.25 x 20
4132530 Arriva PTCA Coronary Balloon Catheter 3.25 x 30
413510 Arriva PTCA Coronary Balloon Catheter 3.5 x 10
413515 Arriva PTCA Coronary Balloon Catheter 3.5 x 15
413520 Arriva PTCA Coronary Balloon Catheter 3.5 x 20
413530 Arriva PTCA Coronary Balloon Catheter 3.5 x 30
413535 Arriva PTCA Coronary Balloon Catheter 3.5 x 35
4137510 Arriva PTCA Coronary Balloon Catheter 3.75 x 10
4137515 Arriva PTCA Coronary Balloon Catheter 3.75 x 15
4137520 Arriva PTCA Coronary Balloon Catheter 3.75 x 20
4137530 Arriva PTCA Coronary Balloon Catheter 3.75 x 30
414010 Arriva PTCA Coronary Balloon Catheter 4.0 x 10
414015 Arriva PTCA Coronary Balloon Catheter 4.0 x 15
414020 Arriva PTCA Coronary Balloon Catheter 4.0 x 20
414030 Arriva PTCA Coronary Balloon Catheter 4.0 x 30
414040 Arriva PTCA Coronary Balloon Catheter 4.0 x 40
414510 Arriva PTCA Coronary Balloon Catheter 4.5 x 10
414515 Arriva PTCA Coronary Balloon Catheter 4.5 x 15
414520 Arriva PTCA Coronary Balloon Catheter 4.5 x 20
414530 Arriva PTCA Coronary Balloon Catheter 4.5 x 30
415020 Arriva PTCA Coronary Balloon Catheter 5.0 x 20
415030 Arriva PTCA Coronary Balloon Catheter 5.0 x 30
415040 Arriva PTCA Coronary Balloon Catheter 5.0 x 40
416020 Arriva PTCA Coronary Balloon Catheter 6.0 x 20
416030 Arriva PTCA Coronary Balloon Catheter 6.0 x 30
416040 Arriva PTCA Coronary Balloon Catheter 6.0 x 40
417020 Arriva PTCA Coronary Balloon Catheter 7.0 x 20
417025 Arriva PTCA Coronary Balloon Catheter 7.0 x 25
417030 Arriva PTCA Coronary Balloon Catheter 7.0 x 30
417040 Arriva PTCA Coronary Balloon Catheter 7.0 x 40
417060 Arriva PTCA Coronary Balloon Catheter 7.0 x 60
442010 Arriva NC Non Compliant Coronary Balloon Catheter 2.0 x 10
442015 Arriva NC Non Compliant Coronary Balloon Catheter 2.0 x 15
442020 Arriva NC Non Compliant Coronary Balloon Catheter 2.0 x 20
442030 Arriva NC Non Compliant Coronary Balloon Catheter 2.0 x 30
442510 Arriva NC Non Compliant Coronary Balloon Catheter 2.5 x 10
442515 Arriva NC Non Compliant Coronary Balloon Catheter 2.5 x 15
442520 Arriva NC Non Compliant Coronary Balloon Catheter 2.5 x 20
442530 Arriva NC Non Compliant Coronary Balloon Catheter 2.5 x 30
443010 Arriva NC Non Compliant Coronary Balloon Catheter 3.0 x 10
443015 Arriva NC Non Compliant Coronary Balloon Catheter 3.0 x 15
443020 Arriva NC Non Compliant Coronary Balloon Catheter 3.0 x 20
443030 Arriva NC Non Compliant Coronary Balloon Catheter 3.0 x 30
443510 Arriva NC Non Compliant Coronary Balloon Catheter 3.5 x 10
443515 Arriva NC Non Compliant Coronary Balloon Catheter 3.5 x 15
443520 Arriva NC Non Compliant Coronary Balloon Catheter 3.5 x 20
443530 Arriva NC Non Compliant Coronary Balloon Catheter 3.5 x 30
444010 Arriva NC Non Compliant Coronary Balloon Catheter 4.0 x 10
444015 Arriva NC Non Compliant Coronary Balloon Catheter 4.0 x 15
444020 Arriva NC Non Compliant Coronary Balloon Catheter 4.0 x 20





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444030 Arriva NC Non Compliant Coronary Balloon Catheter 4.0 x 30
444510 Arriva NC Non Compliant Coronary Balloon Catheter 4.5 x 10
444515 Arriva NC Non Compliant Coronary Balloon Catheter 4.5 x 15
444520 Arriva NC Non Compliant Coronary Balloon Catheter 4.5 x 20
444530 Arriva NC Non Compliant Coronary Balloon Catheter 4.5 x 30
4520100-150 Forte Long Balloon Catheter 2.0 x 100
4520150-150 Forte Long Balloon Catheter 2.0 x 150
4520200-150 Forte Long Balloon Catheter 2.0 x 200
4525100-150 Forte Long Balloon Catheter 2.5 x 100
4525150-150 Forte Long Balloon Catheter 2.5 x 150
4530150-150 Forte Long Balloon Catheter 3.0 x 150
4530200-150 Forte Long Balloon Catheter 3.0 x 200
4535100-150 Forte Long Balloon Catheter 3.5 x 100
4535150-150 Forte Long Balloon Catheter 3.5 x 150
4535200-150 Forte Long Balloon Catheter 3.5 x 150
4540100-150 Forte Long Balloon Catheter 4.0 x 100
4540150-150 Forte Long Balloon Catheter 4.0 x 150
4540200-150 Forte Long Balloon Catheter 4.0 x 200
4545100-150 Forte Long Balloon Catheter 4.5 x 100
4545150-150 Forte Long Balloon Catheter 4.5 x 150
4545200-150 Forte Long Balloon Catheter 4.5 x 200
4550100-150 Forte Long Balloon Catheter 5.0 x 100
4550150-150 Forte Long Balloon Catheter 5.0 x 150
4555150-150 Forte Long Balloon Catheter 5.5 x 150
4555200-150 Forte Long Balloon Catheter 5.5 x 200
4560100-150 Forte Long Balloon Catheter 6.0 x 100
4560150-150 Forte Long Balloon Catheter 6.0 x 150
4560200-150 Forte Long Balloon Catheter 6.0 x 200
4565100-150 Forte Long Balloon Catheter 6.5 x 100
4565150-150 Forte Long Balloon Catheter 6.5 x 150
4565200-150 Forte Long Balloon Catheter 6.5 x 200
774020-100 Hercules PTA Peripheral Balloon Catheter 4.0 x 20
775020-100 Hercules PTA Peripheral Balloon Catheter 5.0 x 20
775040-100 Hercules PTA Peripheral Balloon Catheter 5.0 x 40
775060-100 Hercules PTA Peripheral Balloon Catheter 5.0 x 60
775080-100 Hercules PTA Peripheral Balloon Catheter 5.0 x 80
776020-135 Hercules PTA Peripheral Balloon Catheter 6.0 x 20
776030-135 Hercules PTA Peripheral Balloon Catheter 6.0 x 30
776040-135 Hercules PTA Peripheral Balloon Catheter 6.0 x 40
776060-135 Hercules PTA Peripheral Balloon Catheter 6.0 x 60
776080-135 Hercules PTA Peripheral Balloon Catheter 6.0 x 80
777020-135 Hercules PTA Peripheral Balloon Catheter 7.0 x 20
777030-135 Hercules PTA Peripheral Balloon Catheter 7.0 x 30
777040-135 Hercules PTA Peripheral Balloon Catheter 7.0 x 40
777060-135 Hercules PTA Peripheral Balloon Catheter 7.0 x 60
777080-135 Hercules PTA Peripheral Balloon Catheter 7.0 x 80
778020-135 Hercules PTA Peripheral Balloon Catheter 8.0 x 20
778030-135 Hercules PTA Peripheral Balloon Catheter 8.0 x 30
778040-135 Hercules PTA Peripheral Balloon Catheter 8.0 x 40
778060-135 Hercules PTA Peripheral Balloon Catheter 8.0 x 60
778080-135 Hercules PTA Peripheral Balloon Catheter 8.0 x 80
779020-135 Hercules PTA Peripheral Balloon Catheter 9.0 x 20
779030-135 Hercules PTA Peripheral Balloon Catheter 9.0 x 30
779040-135 Hercules PTA Peripheral Balloon Catheter 9.0 x 40
779060-135 Hercules PTA Peripheral Balloon Catheter 9.0 x 60
779080-135 Hercules PTA Peripheral Balloon Catheter 9.0 x 80
7710020-135 Hercules PTA Peripheral Balloon Catheter 10.0 x 20
7710030-135 Hercules PTA Peripheral Balloon Catheter 10.0 x 30





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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

(Two Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer
INSITU TECHNOLOGIES, INC.
539 Phalen Blvd
Saint Paul, MN USA 55130

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.

Robin W. Newman MSN EdD CPNP
Director
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 27, 2017 to September 26, 2019.





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Name of Manufacturer

INSITU TECHNOLOGIES, INC.
539 Phalen Blvd
Saint Paul, MN USA 55130

Name of Product(s)

Rainbow Catheter 816JL30a Judkins Left 3.0 6F
Rainbow Catheter 816JL35a Judkins Left 3.5 6F
Rainbow Catheter 815JL40RTa Judkins Left 4.0 Relaxed Tip 5F
Rainbow Catheter 816JL40RTa Judkins Left 4.0 Relaxed Tip 6F
Rainbow Catheter 815JL40STa Judkins Left 4.0 Short Tip 5F
Rainbow Catheter 816JL40STa Judkins Left 4.0 Short Tip 6F
Rainbow Catheter 815JL45a Judkins Left 4.5 5F
Rainbow Catheter 816JL45a Judkins Left 4.5 6F
Rainbow Catheter 815JL50a Judkins Left 5.0 5F
Rainbow Catheter 816JL50a Judkins Left 5.0 6F
Rainbow Catheter 815P145-8Ha Pigtail 145° 8 Side holes 5F
Rainbow Catheter 816P145-8Ha Pigtail 145° 8 Side holes 6F
Rainbow Catheter 815JR45a Judkins Right 4.5 5F
Rainbow Catheter 816JR45a Judkins Right 4.5 6F
Rainbow Catheter 815P155-8Ha Pigtail 155° 8 Side holes 5F
Rainbow Catheter 816P155-8Ha Pigtail 155° 8 Side holes 6F
Rainbow Catheter 816P155-10Ha Pigtail 155° 10 Side holes 6F
Rainbow Catheter 815JR30a Judkins Right 3.0 5F
Rainbow Catheter 816JR30a Judkins Right 3.0 6F
Rainbow Catheter 815JR35a Judkins Right 3.5 5F
Rainbow Catheter 815JR40a Judkins Right 4.0 5F
Rainbow Catheter 815JR50a Judkins Right 5.0 5F
Rainbow Catheter 816JR50a Judkins Right 5.0 6F
Rainbow Catheter 815P-8Ha Pigtail Straight 8 Side holes 5F
Rainbow Catheter 816P-8Ha Pigtail Straight 8 Side holes 6F
Rainbow Catheter 815MP40P145L110a TriPack JL4.0/JR4.0/Pigtail 145° 5F
Rainbow Catheter 816MP40P145L110a TriPack JL4.0/JR4.0/Pigtail 145° 6F
Rainbow Catheter 815MP40P155L110a TriPack JL4.0/JR4.0/Pigtail 155° 5F
Rainbow Catheter 816MP40P155L110a TriPack JL4.0/JR4.0/Pigtail 155° 6F
Rainbow Catheter 815MP40PL110a TriPack JL4.0/JR4.0/Pigtail Straight 5F
Rainbow Catheter 816MP40PL110a TriPack JL4.0/JR4.0/Pigtail Straight 6F
Rainbow Catheter 81R5RH 5F Liver
Rainbow Catheter 81R6RH 6F Liver
Rainbow Catheter 81R5RS 5F Spleen
Rainbow Catheter 81R6RS 6F Spleen
Rainbow Catheter 81R5RLG 5F Left Stomach
Rainbow Catheter 81R6RLG 6F Left Stomach
Rainbow Catheter 81R5COBI 5F Cobra I
Rainbow Catheter 81R6COBI 6F Cobra I
Rainbow Catheter 81R6MPB1 6F Multipurpose B1
Rainbow Catheter 81R5MPB2 5F Multipurpose B2
Rainbow Catheter 81R6MPB2 6F Multipurpose B2
Rainbow Catheter 81R5VERT 5F Vertebral Artery
Rainbow Catheter 81R6VERT 6F Vertebral Artery
Rainbow Catheter 81R5SIMSI 5F Simmons Sidewinder I
Rainbow Catheter 81R6SIMSI 6F Simmons Sidewinder I
Rainbow Catheter 81R5HHI 5F Headhunter I
Rainbow Catheter 81R6HHI 6F Headhunter I
Rainbow Catheter 81R5HHIII 5F Headhunter III
Rainbow Catheter 81R6HHIII 6F Headhunter III
Rainbow Catheter 81R5VISC 5F Visceral
Rainbow Catheter 81R6VISC 6F Visceral





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Rainbow Catheter 81R5COBII 5F Cobra II
Rainbow Catheter 81R6COBII 6F Cobra II
Rainbow Catheter 81R5COBIII 5F Cobra III
Rainbow Catheter 81R6COBIII 6F Cobra III
Rainbow Catheter 81R5MPA1 5F Multipurpose A1
Rainbow Catheter 81R6MPA1 6F Multipurpose A1
Rainbow Catheter 81R5MPA2 5F Multipurpose A2
Rainbow Catheter 81R6MPA2 6F Multipurpose A2
Rainbow Catheter 81R5MPB1 5F Multipurpose B1
Rainbow Catheter 81R5SIMSII 5F Simmons Sidewinder II
Rainbow Catheter 81R6SIMSII 6F Simmons Sidewinder II
Rainbow Catheter 81R5SIMSIII 5F Simmons Sidewinder III
Rainbow Catheter 81R6SIMSIII 6F Simmons Sidewinder III
Rainbow Catheter 81R5MIK 5F Mikaelsson Pulmonary
Rainbow Catheter 81R6MIK 6F Mikaelsson Pulmonary
Rainbow Catheter 81R5ST 5F Straight
Rainbow Catheter 81R6ST 6F Straight
Rainbow Catheter 81R5RENDC 5F Renal Double Curve
Rainbow Catheter 81R6RENDC 6F Renal Double Curve
Rainbow Catheter 81R5UTER 5F Uterine Artery
Rainbow Catheter 81R6UTER 6F Uterine Artery
Rainbow Catheter 81R5RIM 5F RIM
Rainbow Catheter 81R6RIM 6F RIM

-----END OF PRODUCT LIST-----





**U.S. FOOD & DRUG
ADMINISTRATION**
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 15385-9-2017

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

(Two Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer/Distributor

INSITU TECHNOLOGIES, INC.
539 Phalen Blvd
Saint Paul, MN USA 55130

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.

Robin W. Newman MSN EdD CPNP
Director
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from September 25, 2017 to September 24, 2019.





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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer/Distributor

INSITU TECHNOLOGIES, INC.
539 Phalen Blvd
Saint Paul, MN USA 55130

Name of Product(s)

Radial Interventional Guidewire 114185-FA 0.014"x185cm Floppy Angled
Radial Interventional Guidewire 114185-FA-H 0.014"x185cm Floppy Angled Hydro. Coat
Radial Interventional Guidewire 114185-FS 0.014"x185cm Floppy Straight
Radial Interventional Guidewire 114185-FS-H 0.014"x185cm Floppy Straight Hydro. Coat
Radial Interventional Guidewire 114185-IA 0.014"x185cm Intermediate Angled
Radial Interventional Guidewire 114185-IA-H 0.014"x185cm Intermediate Angled Hydro. Coat
Radial Interventional Guidewire 114185-IS 0.014"x185cm Intermediate Straight
Radial Interventional Guidewire 114185-IS-H 0.014"x185cm Intermediate Straight Hydro. Coat
Radial Interventional Guidewire 114185-STA 0.014"x185cm Standard Angled
Radial Interventional Guidewire 114185-STA-H 0.014"x185cm Standard Angled Hydro. Coat
Radial Interventional Guidewire 114185-ST 0.014"x185cm Standard Straight
Radial Interventional Guidewire 114185-ST-H 0.014"x185cm Standard Straight Hydro. Coat
Radial Interventional Guidewire 114185-XA 0.014"x185cm X-tra Support Angled
Radial Interventional Guidewire 114185-XA-H 0.014"x185cm X-tra Support Angled Hydro. Coat
Radial Interventional Guidewire 114185-XS 0.014"x185cm X-tra Support Straight
Radial Interventional Guidewire 114185-XS-H 0.014"x185cm X-tra Support Straight Hydro. Coat
Radial Interventional Guidewire 114300-FA 0.014"x300cm Floppy Angled
Radial Interventional Guidewire 114300-FA-H 0.014"x300cm Floppy Angled Hydro. Coat
Radial Interventional Guidewire 114300-FS 0.014"x300cm Floppy Straight
Radial Interventional Guidewire 114300-FS-H 0.014"x300cm Floppy Straight Hydro. Coat
Radial Interventional Guidewire 114300-IA 0.014"x300cm Intermediate Angled
Radial Interventional Guidewire 114300-IA-H 0.014"x300cm Intermediate Angled Hydro. Coat
Radial Interventional Guidewire 114300-IS 0.014"x300cm Intermediate Straight
Radial Interventional Guidewire 114300-IS-H 0.014"x300cm Intermediate Straight Hydro. Coat
Radial Interventional Guidewire 114300-STA 0.014"x300cm Standard Angled
Radial Interventional Guidewire 114300-STA-H 0.014"x300cm Standard Angled Hydro. Coat
Radial Interventional Guidewire 114300-ST 0.014"x300cm Standard Straight
Radial Interventional Guidewire 114300-ST-H 0.014"x300cm Standard Straight Hydro. Coat
Radial Interventional Guidewire 114300-XA 0.014"x300cm X-tra Support Angled
Radial Interventional Guidewire 114300-XA-H 0.014"x300cm X-tra Support Angled Hydro. Coat
Radial Interventional Guidewire 114300-XS 0.014"x300cm X-tra Support Straight
Radial Interventional Guidewire 114300-XS-H 0.014"x300cm X-tra Support Straight Hydro. Coat
Radial Diagnostic Guidewire 221150-J 0.021"x150cm J Tip PTFE Coat
Radial Diagnostic Guidewire 221150-S 0.021"x150cm Straight Tip PTFE Coat
Radial Diagnostic Guidewire 225150-J 0.025"x150cm J Tip PTFE Coat
Radial Diagnostic Guidewire 225150-S 0.025"x150cm Straight Tip PTFE Coat
Radial Diagnostic Guidewire 232150-J 0.032"x150cm J Tip PTFE Coat
Radial Diagnostic Guidewire 232150-S 0.032"x150cm Straight Tip PTFE Coat
Radial Diagnostic Guidewire 232180-J 0.032"x180cm J Tip PTFE Coat
Radial Diagnostic Guidewire 232180-S 0.032"x180cm Straight Tip PTFE Coat
Radial Diagnostic Guidewire 232260-J 0.032"x260cm J Tip PTFE Coat
Radial Diagnostic Guidewire 232260-S 0.032"x260cm Straight Tip PTFE Coat
Radial Diagnostic Guidewire 235150-J 0.035"x150cm J Tip PTFE Coat
Radial Diagnostic Guidewire 235150-S 0.035"x150cm Straight Tip PTFE Coat
Radial Diagnostic Guidewire 235180-J 0.035"x180cm J Tip PTFE Coat
Radial Diagnostic Guidewire 235180-S 0.035"x180cm Straight Tip PTFE Coat
Radial Diagnostic Guidewire 235260-J 0.035"x260cm J Tip PTFE Coat
Radial Diagnostic Guidewire 235260-S 0.035"x260cm Straight Tip PTFE Coat
Radial Diagnostic Guidewire 238150-J 0.038"x150cm J Tip PTFE Coat
Radial Diagnostic Guidewire 238150-S 0.038"x150cm Straight Tip PTFE Coat
Radial Diagnostic Guidewire 238180-J 0.038"x180cm J Tip PTFE Coat
Radial Diagnostic Guidewire 238180-S 0.038"x180cm Straight Tip PTFE Coat





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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

Radial Diagnostic Guidewire 238260-J 0.038"x260cm J Tip PTFE Coat
Radial Diagnostic Guidewire 238260-S 0.038"x260cm Straight Tip PTFE Coat
Raptor Hydro. Coat Nitinol Guidewire 318150-STA 0.018"x150cm Standard Angled
Raptor Hydro. Coat Nitinol Guidewire 318150-STs 0.018"x150cm Standard Straight
Raptor Hydro. Coat Nitinol Guidewire 318185-STA 0.018"x185cm Standard Angled
Raptor Hydro. Coat Nitinol Guidewire 318185-STs 0.018"x185cm Standard Straight
Raptor Hydro. Coat Nitinol Guidewire 318260-STA 0.018"x260cm Standard Angled
Raptor Hydro. Coat Nitinol Guidewire 318260-STs 0.018"x260cm Standard Straight
Raptor Hydro. Coat Nitinol Guidewire 335150-SBA 0.035"x150cm STIFF BODY Angled
Raptor Hydro. Coat Nitinol Guidewire 335150-SBS 0.035"x150cm STIFF BODY Straight
Raptor Hydro. Coat Nitinol Guidewire 335150-STA 0.035"x150cm Standard Angled
Raptor Hydro. Coat Nitinol Guidewire 335150-STs 0.035"x150cm Standard Straight
Raptor Hydro. Coat Nitinol Guidewire 335185-SBA 0.035"x185cm STIFF BODY Angled
Raptor Hydro. Coat Nitinol Guidewire 335185-SBS 0.035"x185cm STIFF BODY Straight
Raptor Hydro. Coat Nitinol Guidewire 335185-STA 0.035"x185cm Standard Angled
Raptor Hydro. Coat Nitinol Guidewire 335185-STs 0.035"x185cm Standard Straight
Raptor Hydro. Coat Nitinol Guidewire 335260-SBA 0.035"x260cm STIFF BODY Angled
Raptor Hydro. Coat Nitinol Guidewire 335260-SBS 0.035"x260cm STIFF BODY Straight
Raptor Hydro. Coat Nitinol Guidewire 335260-STA 0.035"x260cm Standard Angled
Raptor Hydro. Coat Nitinol Guidewire 335260-STs 0.035"x260cm Standard Straight
Raptor Hydro. Coat Nitinol Guidewire 338150-STA 0.038"x150cm Standard Angled
Raptor Hydro. Coat Nitinol Guidewire 338150-STs 0.038"x150cm Standard Straight
Raptor Hydro. Coat Nitinol Guidewire 338185-STA 0.038"x185cm Standard Angled
Raptor Hydro. Coat Nitinol Guidewire 338185-STs 0.038"x185cm Standard Straight
Raptor Hydro. Coat Nitinol Guidewire 338260-STA 0.038"x260cm Standard Angled
Raptor Hydro. Coat Nitinol Guidewire 338260-STs 0.038"x260cm Standard Straight
21001-25 InSitu-InTrac™ Endoflator
22000 InSitu Torque Device
23000 InSitu 3 Port Manifold
23001 InSitu 2 Port Manifold
24001 InSitu Double-Click™ Hemostasis Y Valve 9F
24003 InSitu Double Y™ Hemostasis Valve 7F
24004 InSitu One-Click™ Hemostasis Y Valve 7F
24005 InSitu Double-Click™ Hemostasis Y Valve 7F
25000 InSitu Hemostasis Valve Kit™
25001 InSitu Easy Cath™
25002 InSitu Easy Cath™ Kit
25003 InSitu Double-Click™ Hemostasis Valve Kit
25005 PTCA Kit #1
25006 PTMC Kit
25007 InSitu Hemostasis Valve Kit #2
29020-FRA 20" High Pressure Contrast Line
29030-FRA 30" High Pressure Contrast Line
29048-FRA 48" High Pressure Contrast Line
-----END OF PRODUCT LIST-----





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INSITU TECHNOLOGIES, INC.

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Saint Paul, MN USA 55130

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Robin W. Newman MSN EdD CPNP
Director
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

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Name of Manufacturer/Distributor

INSITU TECHNOLOGIES, INC.

539 Phalen Blvd

Saint Paul, MN USA 55130

Name of Product(s)

StarFlex Sheath Radial Introducer Kit 27511-R 5F 11cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Radial Introducer Kit 27523-R 5F 23cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Radial Introducer Kit 27611-R 6F 11cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Radial Introducer Kit 27623-R 6F 23cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Radial Introducer Kit 27711-R 7F 11cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Radial Introducer Kit 27723-R 5F 23cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Femoral Introducer Kit 27511-F 5F 11cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Femoral Introducer Kit 27523-F 5F 23cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Femoral Introducer Kit 27611-F 6F 11cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Femoral Introducer Kit 27623-F 6F 23cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Femoral Introducer Kit 27711-F 7F 11cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Femoral Introducer Kit 27723-F 7F 23cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Femoral Introducer Kit 27811-F 8F 11cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Femoral Introducer Kit 27823-F 8F 23cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Femoral Introducer Kit 27911-F 9F 11cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Femoral Introducer Kit 27923-F 9F 23cm Sheath, Dilator, Mini Guidewire & Needle
StarFlex Sheath Pediatric Introducer Kit 274575-P 4F 5.75cm Sheath, Dilator, Mini Guidewire & Needle

-----END OF PRODUCT LIST-----

