

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by *Carl Fischer, Ph.D*

3. acting in the capacity of *Director, Division of International Compliance Operations*

4. bears the seal/stamp of *U. S. Department of Health and Human Services*

Certified

5. at Washington, D.C.

6. the *sixteenth* of December, 2016

7. by *Assistant Authentication Officer, United States Department of State*

8. No. *17010871-3*

9. Seal/Stamp:

10. Signature:

Veda Matthews

Veda Matthews



Certificate No. 1951-11-2016

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

(Four Pages)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

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 product(s) listed above.

Carl Fischer, Ph.D.
Director
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate is valid from November 18, 2016 to November 17, 2018.



141902 1/2



Certificate No. 1951-11-2016

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Legal Manufacturer

CORDIS CORPORATION
14201 N.W. 60TH AVE.
Miami Lakes, FL USA 33014

Manufacturing Site

CORDIS DE MEXICO, S.A. DE C.V.
Calle Circuito Interior Norte #1820
PARQUE INDUSTRIAL SALVARCAR
Ciudad Juarez, Chihuahua MEXICO CP 32574

----END OF MANUFACTURER/DISTRIBUTOR LIST----



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

Certificate No. 1951-11-2016

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 4

Name of Manufacturer

Legal Manufacturer

CORDIS CORPORATION
14201 N.W. 60TH AVE.
Miami Lakes, FL USA 33014

Manufacturing Site

CORDIS DE MEXICO, S.A. DE C.V.
Calle Circuito Interior Norte #1820
PARQUE INDUSTRIAL SALVARCAR
Ciudad Juarez, Chihuahua MEXICO CP 32574

Name of Product(s)

Brite Tip Catheter Sheath Introducer

401011M Brite Tip Sheath 10F 11CM
401023M Brite Tip Sheath 10F 23CM
401111M Brite Tip Sheath 11F 11CM
401123M Brite Tip Sheath 11F 23CM
401411M Brite Tip Sheath 4F 11CM
401423M Brite Tip Sheath 4F 23CM
401511M Brite Tip Sheath 5F 11CM
401523M Brite Tip Sheath 5F 23CM
401535M Brite Tip Sheath 5F 35CM
401545M Brite Tip Sheath 5F 45CM
401555M Brite Tip Sheath 5F 55CM
401605M CSI Brite Tip 6F 5.5CM
401611M CSI Brite Tip 6F 11CM STR
401623M CSI Brite Tip 6F 23CM STR
401635M CSI Brite Tip 6F 35CM STR
401645M CSI Brite Tip 6F 45CM STR
401655M CSI Brite Tip 6F 55CM STR
401690M CSI Brite Tip 6F 90CM
401705M CSI Brite Tip 7F 5.5 CM
401711M CSI Brite Tip 7F 11CM STR
401723M CSI Brite Tip 7F 23CM STR
401735M CSI Brite Tip 7F 35CM STR
401745M CSI Brite Tip 7F 45CM STR
401755M CSI Brite Tip 7F 55CM STR
401790M CSI Brite Tip 7F 90CM
401805M CSI Brite Tip 8F 5.5 CM
401811M CSI Brite Tip 8F 11CM STR
401823M CSI Brite Tip 8F 23CM STR
401835M CSI Brite Tip 8F 35CM STR
401845M CSI Brite Tip 8F 45CM STR
401855M CSI Brite Tip 8F 55CM STR
401890M CSI Brite Tip 8F 90CM
401911M CSI 9F Brite Tip 11CM
401923M CSI 9F Brite Tip 23CM
401935M CSI 9F Brite Tip 35CM
401945M CSI 9F Brite Tip 45CM
401955M CSI 9F Brite Tip 55CM

—
Avanti Plus Catheter Sheath Introducer

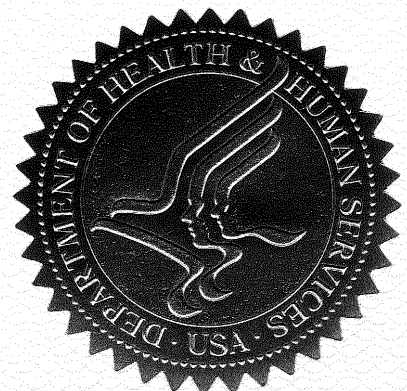
402604A AVANTI+ 4FR STD NO GW
402604P AVANTI+ 4 FR OPTA WITH GW 5.5 CM
402604R AVANTI+ 4 FR OPTA WO GW 5.5 CM
402604T AVANTI+ 4FR MID LENGTH
402604X AVANTI+ 4FR STD with .035 GW



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

Certificate No. 1951-11-2016**Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 4**

402605A AVANTI+ 5FR STD NO GW
402605P AVANTI+ 5 FR OPTA WITH GW 5.5 CM
402605R AVANTI+ 5 FR OPTA WO GW 5.5 CM
402605T AVANTI+ 5FR MID LENGTH
402605X AVANTI+ 5FR STD with .035 GW
402606A AVANTI+ 6FR STD NO GW
402606P AVANTI+ 6 FR OPTA WITH GW 5.5 CM
402606R AVANTI+ 6 FR OPTA WO G W 5.5 CM
402606T AVANTI+ 6FR MID LENGTH
402606X AVANTI+ 6FR STD with .035 GW
402607A AVANTI+ 7FR STD NO GW
402607P AVANTI+ 7FR OPTA WITH GW 5.5 CM
402607R AVANTI+ 7FR OPTA WO GW 5.5 CM
402607T AVANTI+ 7FR MID LENGTH
402607X AVANTI+ 7FR STD with .035 GW
402608A AVANTI+ 8FR STD NO GW
402608T AVANTI+ 8FR MID LENGTH
402608X AVANTI+ 8FR STD with .035 GW
402609A AVANTI+ 9FR OPTA NO GW 11 CM
402609T AVANTI+ 9FR OPTA W/OBT- 23 CM
402609X AVANTI+ 9FR with .035 GW
402610A AVANTI+ 10FR OPTA NO GW 11 CM
402610T AVANTI+ 10FR OPTA W/OBT- 23 CM
402610X AVANTI+ 10FR with .035 GW
402611T AVANTI+ 11FR OPTA W/OBT- 23 CM
402611X AVANTI+ 11FR with .035 GW
402655P CSI AVANTI+ ENDOVASCULAR .035
402655X AVANTI+ 5.5FR with .035 GW
402656P CSI AVANTI+ ENDOVASCULAR .035
402656T AVANTI+ 6.5FR MID LENGTH
402656X AVANTI+ 6.5FR with .035 GW
402657P CSI AVANTI+ ENDOVASCULAR .035
402658A AVANTI+ 8.54FR STD NO GW
402658P CSI AVANTI+ ENDOVASCULAR .035
504504S V D #4. 021 14.5 CM
504604A AV + 4FR STD W/O
504604P CSI AVANTI + 4F BRACHIAL
504604S 4F AVANTI+ CSIS PED THIN
504604T CSI AVANTI+ 4F MID W/O GW&OBT
504604X AVANTI + 4F STD W/GW
504605A AV + 5FR STD W/O
504605P CSI AVANTI + 5F BRACHIAL
504605S 5F AVANTI+ CSIS PED THIN
504605T CSI AVANTI+ 5F MID W/O GW&OBT
504605X AVANTI + 5F STD W/GW
504606A CSI AVANTI+ 6F STD W/O GW&OBT
504606D 6FR MID W/OBT
504606P CSI AVANTI + 6F BRACHIAL
504606S 6F AVANTI+ CSIS PED THIN
504606T CSI AVANTI+ 6F MID W/O GW&OBT
504606V 6F AVANTI+ V.P. SHEATH
504606X CSI AVANTI+ 6F STD W/GW NO OBT
504607A CSI AVANTI+ 7F STD W/O GW&OBT
504607D 7FR MID W/OBT
504607T CSI AVANTI+ 7F MID W/O GW&OBT
504607V 7F AVANTI+ V.P. SHEATH
504607X CSI AVANTI+ 7F STD W/GW NO OBT
504608A CSI AVANTI+ 8F STD W/O GW&OBT



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

Certificate No. 1951-11-2016**Certificate to Foreign Government - Name of Product(s) Attachment Page 3 of 4**

504608D 8FR MID W/OBT
504608T CSI AVANTI+ 8F MID W/O GW&OBT
504608V 8F AVANTI+ V.P. SHEATH
504608X CSI AVANTI+ 8F STD W/GW NO OBT
504609A AV + 9FR STD W/O
504609D 9FR MID W/OBT
504609T CSI AVANTI+ 9F MID W/O GW&OBT
504609X CSI AVANTI+ 9F STD W/GW NO OBT
504610A AVANTI+ 10FR STD NO G/W
504610T CSI AVANTI+ CSI
504610X CSI AVANTI+ 10F STD W/GW
504611A AVANTI+ 11FR STD NO G/W
504611T CSI AVANTI + 11F MID W/O GW
504611X CSI AVANTI + 11F STD W/GW
504655A AVANTI+ 5.5 STD NO G/W
504655T AVANTI+ 5.5 MID NO G/W
504655X AVANTI+ 5.5 STD NO OBT
504656A AVANTI+ 6.5 STD NO G/W
504656T AVANTI+ 6.5 MID NO G/W
504656X AVANTI+ 6.5 STD NO OBT
504657A AVANTI+ 7.5 STD NO G/W
504657T AVANTI+ 7.5 MID NO G/W
504657X AVANTI+ 7.5 STD NO OBT
504658A AVANTI+ 8.5 STD NO G/W
504658T AVANTI+ 8.5 MID NO G/W
504658X AVANTI+ 8.5 STD NO OBT

—
Transradial Kit

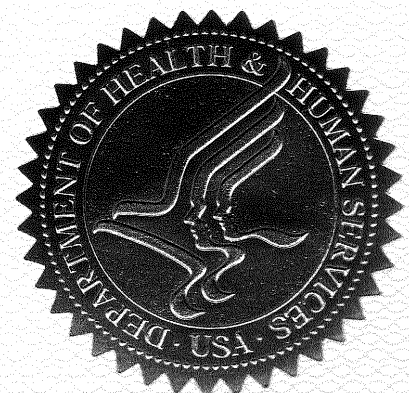
504614Z AVANTI+ 4FR 11CM XRADIAL
504615Z AVANTI+ 5FR 11CM XRADIAL
504616Z AVANTI+ 6FR 11CM XRADIAL
504617Z AVANTI+ 7FR 11CM XRADIAL
504624Z AVANTI+ 4FR 23CM XRADIAL
504625Z AVANTI+ 5FR 23CM XRADIAL
504626Z AVANTI+ 6FR 23CM XRADIAL
504627Z AVANTI+ TRANSRAD KIT 23CM

—
Vessel Dilators

504404X VSL DIL 4F .035GW
504405X VSL DIL 5F .035GW
504406X VSL DIL 6F .035GW
504407X V D #7. 035 19 CM
504408X V D #8. 035 19 CM
504409X V D #9. 035 19 CM
504504S V D #4. 021 14.5 CM
504505S ACCS VESSEL DILATOR 5F .021GW
504505X VSL DIL 5F .038GW
504506S V D #6. 021 15.8 CM
504506X VSL DIL 6F .038GW
504507X VSL DIL 7F .038GW
504508X VSL DIL 8F .038GW
504509X VSL DIL 9F .038GW

—
Obturator

502188 ACCS OBTURATOR 4F 13.5CM
502189 ACCS OBTURATOR 4F 26CM
502190 ACCS OBTURATOR 5F 13.5CM
502191 ACCS OBTURATOR 6F 13.5CM



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

Certificate No. 1951-11-2016

Certificate to Foreign Government - Name of Product(s) Attachment Page 4 of 4

502192 ACCS OBTURATOR 7F 13.5CM

502194 OBT 14.5 FR 8

502196 ACCS OBTURATOR 5F 26CM

502197 ACCS OBTURATOR 6F 26CM

502198 ACCS OBTURATOR 7F 26CM

502200 OBT 27.5 FR 8

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

