



**Certificate No. 7310-9-2015**

**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**

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 September 15, 2015 to September 14, 2017.**





**Certificate No. 7310-9-2015**

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

**Name of Manufacturer**

**Legal Manufacturer/Manufacturer**

AGA MEDICAL CORP.  
5050 NATHAN LANE NORTH  
Plymouth, MN USA 55442

**Manufacturing Facility**

St. Jude Medical Costa Rica Ltda.  
Edificio #44 Calle 0, Ave. 2  
Zona Franca Coyol  
El Coyol, Alajuela COSTA RICA 1897-4050

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





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

**Name of Manufacturer**

**Legal Manufacturer/Manufacturer**

AGA MEDICAL CORP.  
5050 NATHAN LANE NORTH  
Plymouth, MN USA 55442

**Manufacturing Facility**

St. Jude Medical Costa Rica Ltda.  
Edificio #44 Calle 0, Ave. 2  
Zona Franca Coyoil  
El Coyoil, Alajuela COSTA RICA 1897-4050

**Name of Product(s)**

Amplatzer® Septal Occluder

- Model #s 9-ASD-004, 9-ASD-005, 9-ASD-006, 9-ASD-007, 9-ASD-008, 9-ASD-009,  
9-ASD-010, 9-ASD-011, 9-ASD-012, 9-ASD-013, 9-ASD-014, 9-ASD-015, 9-ASD-016,  
9-ASD-017, 9-ASD-018, 9-ASD-019, 9-ASD-020, 9-ASD-022, 9-ASD-024, 9-ASD-026,  
9-ASD-028, 9-ASD-030, 9-ASD-032, 9-ASD-034, 9-ASD-036, 9-ASD-038

**Name of Manufacturer**

**Legal Manufacturer/Manufacturer**

AGA MEDICAL CORP.  
5050 NATHAN LANE NORTH  
Plymouth, MN USA 55442

**Name of Product(s)**

Amplatzer Multifenestrated Septal Occluder "Cribriform"

- Model #s 9-ASD-MF-018, 9-ASD-MF-025, 9-ASD-MF-030, 9-ASD-MF-035

Amplatzer Duct Occluder

- Model #s 9-PDA-003, 9-PDA-004, 9-PDA-005, 9-PDA-006, 9-PDA-007

Amplatzer Duct Occluder II

- Model #s 9-PDA2-03-04, 9-PDA2-03-06, 9-PDA2-04-04, 9-PDA2-04-06,  
9-PDA2-05-04, 9-PDA2-05-06, 9-PDA2-06-04, 9-PDA2-06-06

Amplatzer Muscular VSD Occluder

- Model #s 9-VSD-MUSC-004, 9-VSD-MUSC-006, 9-VSD-MUSC-008, 9-VSD-MUSC-010,  
9-VSD-MUSC-012, 9-VSD-MUSC-014, 9-VSD, MUSC-016, 9-VSD-MUSC-018

Amplatzer Vascular Plug

- Model #s 9-PLUG-004, 9-PLUG-006, 9-PLUG-008, 9-PLUG-010, 9-PLUG-012,  
9-PLUG-014, 9-PLUG-016

Amplatzer Vascular Plug II

- Model #s 9-AVP2-003, 9-AVP2-004, 9-AVP2-006, 9-AVP2-008, 9-AVP2-010,  
9-AVP2-012, 9-AVP2-014, 9-AVP2-016, 9-AVP2-018, 9-AVP2-020, 9-AVP2-022

Amplatzer Vascular Plug 4

- Model #s 9-AVP038-004, 9-AVP038-005, 9-AVP038-006, 9-AVP038-007, 9-AVP038-008

Amplatzer Delivery System

- Model #s 9-DEL-6F-45/60, 9-DEL-7F-45/60, 9-DEL-7F-45/80, 9-DEL-8F-45/60,  
9-DEL-8F-45/80, 9-DEL-5F-180/60, 9-DEL-6F-180/80, 9-DEL-7F-180/80, 9-DEL-8F-180/80,  
9-DEL-9F-180/80, 9-DEL-9F-45/80, 9-DEL-10F-45/80, 9-DEL-12F-45/80

Amplatzer Exchange System







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- Model #s 9-EXCH-9F-45/80, 9-EXCH-12F-45/80, 9-EXCH-6F-180/80, 9-EXCH-8F-180/80

**Amplatzer TorqVue Exchange System**

- Model #s 9-EITV09F45/80, 9-EITV12F45/80, 9-EITV06F180/80, 9-EITV-8F180/80,  
9-EITV10F180/80

**Amplatzer TorqVue Delivery System**

- Model #s 9-ITV06F45/60, 9-ITV07F45/60, 9-ITV07F45/80, 9-ITV08F45/60,  
9-ITV08F45/80, 9-ITV09F45/80, 9-ITV10F45/80, 9-ITV12F45/80, 9-ITV05F180/60,  
9-ITV06F180/60, 9-ITV06F180/80, 9-ITV07F180/80, 9-ITV08F180/80, 9-ITV-9F180/80

**Amplatzer TorqVue LP Delivery System**

- Model #s 9-TVLP4F90/060, 9-TVLP4F90/080, 9-TVLP5F90/060, 9-TVLP5F90/080

**Amplatzer TorqVue 45 x 45 Delivery Sheath**

- Model #s 9-TV45X45-09F-100, 9-TV45X45-10F-100, 9-TV45X45-12F-100,  
9-TV45X45-13F-100, 9-TV45X45-14F-100

**Amplatzer TorqVue 2 Delivery Sheath**

- Model #s 9-TV2-05F120 5 F-120 cm, 9-TV2-06F120 6 F-120 CM, 9-TV2-07F120 7 F-120 cm

**Amplatzer TorqVue 3 Delivery Sheath**

- Model #s 9-TV3-08F54, 9-TV3-08F104

**Amplatzer TorqVue LA Delivery Sheath**

- Model #s 9-TV-LA1-09F-080, 9-TV-LA1-10F-080, 9-TV-LA1-12F-080, 9-TV-LA1-13F-080,  
9-TV-LA1-14F-080, 9-TV-LA2-09F-080, 9-TV-LA2-10F-080, 9-TV-LA2-12F-080,  
9-TV-LA2-13F-080, 9-TV-LA2-14F-080

**Amplatzer Sizing Balloon II**

- Model #s 9-SB-018, 9-SB-024, 9-SB-034

**Amplatzer Sizing Plate**

- Model # 9-ASD-SZP

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

