ST. JUDE MEDICAL

SJM Declaration of Conformity

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:

AGA Medical Corporation
5050 Nathan Lane North
Plymouth, Minnesota 55442, USA

European Representative:

St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium

Product Type:

Cardiac Occluder

Product Name(s):

AMPLATZER Septal Occluder
AMPLATZER Multi-Fenestrated Septal Occluder - "Cribriform"
AMPLATZER PFO Occluder

Model Number(s):

Product	Model Numbers	Original CE Mark Date
AMPLATZER Septal Occluder	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, 9-ASD-040	24 February 1998
AMPLATZER Multi-Fenestrated Septal Occluder – "Cribriform"	9-ASD-MF-018, 9-ASD-MF-025, 9-ASD-MF-030, 9-ASD-MF-035, 9-ASD-MF-040	2 September 2002
AMPLATZER PFO Occluder	9-PFO-018, 9-PFO-025, 9-PFO-030, 9-PFO-035	24 February 1998

Signature:

Lisa Becker
Senior Director, Regulatory Affairs

21 Feb 18
Issue Date

Digitally signed by Ceaicovschi Tudor
Date: 2023.07.11 11:54:57 EEST
Reason: MoldSign Signature
Location: Moldova

ST. JUDE MEDICAL

SJM Declaration of Conformity

Classification:	Class III per Annex II, Rule 8
GMDN Code(s):	45418
EC Design Certificate No and Expiration Date:	Certificate No: CE 594291 Expiration Date: 23 February 2023
Annex II, Clause 3 Certificate No and Expiration Date:	Certificate No: CE 590631 Expiration Date: 23 February 2023
Applicable Quality System Standards:	ISO 13485
Notified Body:	BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP UK
Notified Body Number:	0086
AMPLATZER Septal Occluder Manufacturing Facilities:	AGA Medical Corporation 5050 Nathan Lane North Plymouth, Minnesota 55442 USA St. Jude Medical, Costa Rica Ltda. Edificio #44, Calle 0, Avenida 2 Zona Franca Coyol, El Coyol, Alajuela, Costa Rica
AMPLATZER Multi-Fenestrated Septal Occluder - "Cribriform" Manufacturing Facility:	AGA Medical Corporation 5050 Nathan Lane North Plymouth, Minnesota 55442 USA
AMPLATZER PFO Occluder Manufacturing Facility:	AGA Medical Corporation 5050 Nathan Lane North Plymouth, Minnesota 55442 USA

Signature:

Lisa Becker
Senior Director, Regulatory Affairs

21 Feb 18
Issue Date

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 594291**

Issued To: **AGA Medical Corporation**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

AMPLATZER Septal Occluder, AMPLATZER Multifenestrated Septal Occluder - "Cribriform" and AMPLATZER PFO Occluder

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2013-02-24** Date: **2018-02-14** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 594291

Issued To:

AGA Medical Corporation
5050 Nathan Lane North
Plymouth
Minnesota
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Amplatzer Septal Occluder:

Device Size (mm)	Model Number	Wire Diameter (mm)/Number of Wires	Distal Disc Diameter (mm)	Proximal Disc Diameter (mm)	Waist Diameter	Waist Length
4	9-ASD-004	.004/72	16	12	4	3
5	9-ASD-005	.004/72	17	13	5	3
6	9-ASD-006	.004/72	18	14	6	3
7	9-ASD-007	.004/72	19	15	7	3
8	9-ASD-008	.004/72	20	16	8	3
9	9-ASD-009	.004/72	21	17	9	3
10	9-ASD-010	.004/72	22	18	10	3
11	9-ASD-011	.005/72	25	21	11	4
12	9-ASD-012	.005/72	26	22	12	4
13	9-ASD-013	.005/72	27	23	13	4
14	9-ASD-014	.005/72	28	24	14	4
15	9-ASD-015	.005/72	29	25	15	4
16	9-ASD-016	.005/72	30	26	16	4

First Issued: **2013-02-24** Date: **2018-02-14** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 594291

Issued To:

AGA Medical Corporation
5050 Nathan Lane North
Plymouth
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USA

Device Size (mm)	Model Number	Wire Diameter (mm)/Number of Wires	Distal Disc Diameter (mm)	Proximal Disc Diameter (mm)	Waist Diameter	Waist Length
17	9-ASD-017	.005/72	31	27	17	4
18	9-ASD-018	.006/72	32	28	18	4
19	9-ASD-019	.006/72	33	29	19	4
20	9-ASD-020	.006/72	34	30	20	4
22	9-ASD-022	.006/72	36	32	22	4
24	9-ASD-024	.006/72	38	34	24	4
26	9-ASD-026	.007/72	40	36	26	4
28	9-ASD-028	.007/72	42	38	28	4
30	9-ASD-030	.007/72	44	40	30	4
32	9-ASD-032	.007/72	46	42	32	4
34	9-ASD-034	.008/72	50	44	34	4
36	9-ASD-036	.008/72	52	46	36	4
38	9-ASD-038	.008/72	54	48	38	4
40	9-ASD-040	.008/72	56	50	40	4

First Issued: **2013-02-24** Date: **2018-02-14** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 594291

Issued To:

AGA Medical Corporation
5050 Nathan Lane North
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USA

Amplatzer Multi-Fenestrated Septal Occluder – "Cribriform":

Device Size (mm)	Model Number	Wire Diameter (mm)/Number of Wires	Disc Diameter (mm)	Diameter of Raised Disc (mm)
18	9-ASD-MF-018	.005/72	18	6
25	9-ASD-MF-025	.005/72	25	13
30	9-ASD-MF-030	.005/72	30	30
35	9-ASD-MF-035	.006/72	35	23
40	9-ASD-MF-040	.006/72	40	40

AMPLATZER PFO Occluder:

Model Number	Device Size (mm)	Right Atrial Disc Diameter (mm)	Left Atrial Disc Diameter (mm)	Waist Length
9-PFO-018	18	18	18	3
9-PFO-025	25	25	18	3
9-PFO-030	30	30	30	3
9-PFO-035	35	35	25	3

First Issued: **2013-02-24** Date: **2018-02-14** Expiry Date: **2023-02-23**

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By Royal Charter

EC Design-Examination Certificate

Supplementary Information to CE 594291

Issued To:

AGA Medical Corporation
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
24 February 2013	10139223	First Issue – Transfer from another Notified Body.
28 May 2013	10141409	Change the surface finish of the nitinol wire from black oxide to chemically etched.
03 February 2014	10144456	Update to Amplatzer Septal Occluder IFU. There are no changes to the intended use.
06 February 2015	10152724	Addition of St. Jude Medical Costa Rica Ltda. as an alternate manufacturing site for the Amplatzer Septal Occluder. Addition of Synergy Health AST, SRL as an alternate sterilization site for the Amplatzer Septal Occluder.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
01 February 2016	10160623	Addition of Sterigenics Willowbrook, IL as a sterilizer.
Current	8872315	Certificate renewal.

First Issued: **2013-02-24** Date: **2018-02-14** Expiry Date: **2023-02-23**

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Abbott

Abbott Medical Declaration of Conformity

Abbott Medical (Abbott) hereby declares that the following Abbott facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of Abbott. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:	Abbott Medical 5050 Nathan Lane North Plymouth, Minnesota 55442, USA
European Representative:	Abbott Medical The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Cardiac Occluder Delivery Kit
Product Name(s):	Amplatzer TorqVue Delivery System Amplatzer TorqVue Exchange System Amplatzer TorqVue 2 Delivery Sheath Amplatzer TorqVue LP Delivery System Amplatzer TorqVue LP Catheter Amplatzer TorqVue Delivery System with Pusher Catheter Amplatzer TorqVue 45°x45° Delivery Sheath Amplatzer Amulet Delivery Sheath Amplatzer Trevisio Intravascular Delivery System

Signature:

Michelle Grossman
Director, Regulatory Affairs

April 21, 2020
Issue Date

Abbott

Abbott Medical Declaration of Conformity

Model Number(s):

Product	Model Numbers	Original CE Mark Date
Amplatzer TorqVue Delivery System	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-ITV13F45/80 9-ITV05F180/60 9-ITV06F180/60 9-ITV06F180/80 9-ITV07F180/80 9-ITV08F180/80 9-ITV09F180/80	10 October 2005
Amplatzer TorqVue Exchange System	9-EITV09F45/80 9-EITV12F45/80 9-EITV06F180/80 9-EITV08F180/80 9-EITV10F180/80	10 October 2005
Amplatzer TorqVue 2 Delivery Sheath	9-TV2-05F120 9-TV2-06F120 9-TV2-07F120	19 February 2010
Amplatzer TorqVue LP Delivery System	9-TVLP4F90/060 9-TVLP4F90/080 9-TVLP5F90/060 9-TVLP5F90/080	07 February 2008
Amplatzer TorqVue LP Catheter	9-TVLPC4F90/080	28 April 2011
Amplatzer TorqVue Delivery System with Pusher Catheter	9-ITVP07F-180/80 9-ITVP08F-180/80 9-ITVP09F-180/80	21 June 2011
Amplatzer TorqVue 45°x45° Delivery Sheath	9-TV45X45-09F-100 9-TV45X45-10F-100 9-TV45X45-12F-100 9-TV45X45-13F-100 9-TV45X45-14F-100	03 December 2008 (9-13 Fr) 24 February 2012 (14 Fr)
Amplatzer Amulet Delivery Sheath	DS-TV45X45-12F-080 DS-TV45X45-14F-080	08 February 2017
Amplatzer Trevisio Intravascular Delivery System	9-ATV06F45/60 9-ATV07F45/60 9-ATV07F45/80 9-ATV08F45/60 9-ATV08F45/80 9-ATV09F45/80 9-ATV10F45/80 9-ATV12F45/80 9-ATV13F45/80	20 April 2020

Signature:

Michelle Grossman
Director, Regulatory Affairs

April 21 2020
Issue Date

Abbott

Abbott Medical Declaration of Conformity

Classification:	Class III (Rule 7) Annex II, Section 4 GHTF Class D
GMDN Code(s):	45419
EC Design Certificate No and Expiration Date:	Certificate No: CE 694956 Expiration Date: 23 February 2023
Annex II, Clause 3 Certificate No and Expiration Date:	Certificate No: CE 694788 Expiration Date: 23 February 2023
Applicable Quality System Standards:	ISO 13485
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
Notified Body Number:	2727

Signature:

Michelle Grossman
Director, Regulatory Affairs

April 21, 2020
Issue Date

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 694956**

Issued To: **Abbott Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

Amplatzer Delivery Systems

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding 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: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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By Royal Charter

EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
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USA

Amplatzer™ TorqVue™ Delivery System			
Intended purpose per IFU: The Amplatzer™ TorqVue™ Delivery System is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Occluder devices.			
Classification: Class III			
Catalogue Number	**Model, Type**		
	Sheath Size (Fr)	**Tip Angle**	**Usable Length (cm)**
9-ITV06F45/60	6	45°	60
9-ITV07F45/60	7	45°	60
9-ITV07F45/80	7	45°	80
9-ITV08F45/60	8	45°	60
9-ITV08F45/80	8	45°	80
9-ITV09F45/80	9	45°	80
9-ITV10F45/80	10	45°	80
9-ITV12F45/80	12	45°	80
9-ITV13F45/80	13	45°	80
9-ITV05F180/60	5	180°	60
9-ITV06F180/60	6	180°	60
9-ITV06F180/80	6	180°	80
9-ITV07F180/80	7	180°	80
9-ITV08F180/80	8	180°	80
9-ITV09F180/80	9	180°	80

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
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USA

Amplatzer™ TorqVue™ Exchange System			
Intended purpose per IFU: The Amplatzer™ TorqVue™ Exchange System is intended for removal of an Amplatzer™ Delivery Sheath and subsequent exchange for an Amplatzer™ Delivery Sheath of equal or larger diameter.			
Classification: Class III			
Catalogue Number	**Model, Type**		
	Sheath Size (Fr)	**Tip Angle**	**Usable Length (cm)**
9-EITV09F45/80	9	45°	80
9-EITV12F45/80	12	45°	80
9-EITV06F180/80	6	180°	80
9-EITV08F180/80	8	180°	80
9-EITV10F180/80	10	180°	80

Amplatzer™ TorqVue™ 2 Delivery Sheath			
Intended purpose per IFU: The Amplatzer™ TorqVue™ 2 Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers and coronary vasculature of the heart or in the peripheral vasculature.			
Classification: Class III			
Catalogue Number	**Model, Type**		
	Sheath Size (Fr)	**Tip Angle**	**Usable Length (cm)**
9-TV2-05F120	5	none	120
9-TV2-06F120	6	none	120
9-TV2-07F120	7	none	120

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
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Amplatzer™ TorqVue™ Delivery System with Pusher Catheter			
Intended purpose per IFU: The Amplatzer™ TorqVue™ Delivery System with Pusher Catheter is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Membranous VSD Occluder device.			
Classification: Class III			
Catalogue Number	**Model, Type**		
	Sheath Size (Fr)	**Tip Angle**	**Usable Length (cm)**
9-ITVP07F180/80	7	180°	80
9-ITVP08F180/80	8	180°	80
9-ITVP09F180/80	9	180°	80

Amplatzer™ TorqVue™ LP Delivery System				
Intended purpose per IFU: The Amplatzer™ TorqVue™ LP Delivery System is intended to facilitate the attachment, loading, delivery, and deployment of the Amplatzer™ devices.				
Classification: Class III				
Catalogue Number	**Model, Type**			
	Device Size (Fr)	**Curve Dimension**	**Length (cm)**	**Delivery Wire Length (cm)**
9-TVLP4F90/060	4	90°	60	160
9-TVLP4F90/080	4	90°	80	195
9-TVLP5F90/060	5	90°	60	160
9-TVLP5F90/080	5	90°	80	195

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
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Amplatzer™ Trevisio™ Intravascular Delivery System			
Intended purpose per IFU: The Amplatzer™ Trevisio™ Intravascular Delivery System is intended to facilitate the attachment, loading, delivery and deployment of the Amplatzer™ Occluder devices.			
Classification: Class III			
Catalogue Number	**Model, Type**		
	Sheath Size (Fr)	**Tip Angle**	**Usable Length (cm)**
9-ATV06F45/60	6	45°	60
9-ATV07F45/60	7	45°	60
9-ATV07F45/80	7	45°	80
9-ATV08F45/60	8	45°	60
9-ATV08F45/80	8	45°	80
9-ATV09F45/80	9	45°	80
9-ATV10F45/80	10	45°	80
9-ATV12F45/80	12	45°	80
9-ATV13F45/80	13	45°	80

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
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USA

Amplatzer™ TorqVue™ LP Catheter				
Intended purpose per IFU: The TorqVue™ LP Catheter is intended to facilitate the loading, delivery, and deployment of Amplatzer™ devices.				
Classification: Class III				
Catalogue Number	**Model, Type**			
	Device Size (Fr)	**Usable Length (cm)**	**Tip Outer Diameter mm (in)**	**Tip Inner Diameter mm (in)**
9-TVLPC4F90/080	4	80	1.40 (.055)	1.17 (0.046)

Amplatzer™ TorqVue™ 45x45 Delivery Sheath		
Intended purpose per IFU: The Amplatzer™ TorqVue™ Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart.		
Classification: Class III		
Catalogue Number	**Model, Type**	
	Sheath Size (Fr)	**Length (cm)**
9-TV45X45-09F-100	9	100
9-TV45X45-10F-100	10	100
9-TV45X45-12F-100	12	100
9-TV45X45-13F-100	13	100
9-TV45X45-14F-100	14	100

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Amplatzer™ Amulet™ Delivery Sheath		
Intended purpose per IFU: The Amplatzer™ Amulet™ Delivery Sheath is intended to provide a pathway through which devices are introduced within the chambers of the heart.		
Classification: Class III		
Catalogue Number	**Model, Type**	
	Sheath Size (Fr)	**Length (cm)**
DS-TV45X45-12F-080	12	80
DS-TV45X45-14F-080	14	80

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 694956

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
03 September 2018	8957249	First Issue. Mirror certificate to CE 594294.
20 February 2019	8243107	Traceable to NB 0086.
20 March 2019	9738457	Addition of Sterigenics US LLC, Salt Lake City, Utah for ETO Sterilization.
16 December 2019	3053900	Addition of Midwest Sterilization Corporation, Jackson, Missouri USA for ETO Sterilization in chambers 1, 2, 3, 6, and 13.
Current	9784335	Extension to scope to include the Amplatzer™ Trevisio™ Intravascular Delivery System. Revision to scope statement to remove "TorqVue" brand name. Reformat product tables. Correction of delivery wire length for Amplatzer™ TorqVue™ LP Delivery System. Correction of tip outer diameter for Amplatzer™ TorqVue™ LP Catheter.

First Issued: **2018-09-03** Date: **2020-04-20** Expiry Date: **2023-02-23**

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ST. JUDE MEDICAL

SJM Declaration of Conformity

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/ECC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:	AGA Medical Corporation 5050 Nathan Lane North Plymouth, Minnesota 55442, USA
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Catheter Guide Wire
Product Name(s):	AMPLATZER Guidewires
Model Number(s):	9-GW-001, 9-GW-002, 9-GW-003, 9-GW-004
Classification:	Class III (Rule 7) Annex II, Section 4 GHTF Class D
GMDN Code(s):	35094
Original CE Mark Date:	22 March 2001 (1-3), 22 Sept 2003 (4, Noodlewire)
EC Certificate No and expiration date:	Certificate No: CE 594293 Expiration Date: 23 Feb 2023
Annex II, Clause 3:	Certificate No: CE 590631 Expiration Date: 23 Feb 2023
Applicable Quality System Standards:	ISO 13485
Notified Body:	BSI Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP UK
Notified Body Number:	0086

Signature:

Lisa Becker
Senior Director, Regulatory Affairs

21Feb18
Issue Date

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 694955**

Issued To: **Abbott Medical**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

AMPLATZER Guidewires

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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

Albert Roossien, Regulatory Lead

First Issued: **2018-09-03** Date: **2019-02-20** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 694955

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Part Number	Description
9-GW-001	JFC-SS Modified J, Fixed, PTFE Coated, Super Stiff
9-GW-002	J1.5FC-SS, Modified J, Fixed, PTFE Coated, Super Stiff
9-GW-003	J9FC-FS-LLLT Fixed Core, Long (20 cm) PTFE Coated, Finger-Straightenable
9-GW-004	Noodlewire Guidewire

First Issued: **2018-09-03** Date: **2019-02-20** Expiry Date: **2023-02-23**

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EC Design-Examination Certificate

Supplementary Information to CE 694955

Issued To:

Abbott Medical
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

Certificate History

Date	Reference Number	Action
03 September 2018	8957249	First Issue. Mirror certificate to CE 594293.
Current	8243107	Traceable to NB 0086.

First Issued: **2018-09-03** Date: **2019-02-20** Expiry Date: **2023-02-23**

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ST. JUDE MEDICAL

SJM Declaration of Conformity

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:	AGA Medical Corpation 5050 Nathan Lane North Plymouth, Minnesota 55442, USA
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Cardiac Catheter, Balloon, Sizing
Product Name(s):	AMPLATZER Sizing Balloon II
Model Number(s):	9-SB-018, 9-SB-024, 9-SB-034
Classification:	Class III (Rule 7) Annex II, Section 4, GHTF Class D
GMDN Code(s):	42417
Original CE Mark Date:	10 June 2005 (24 mm) 02 Sept 2005 (18, 34 mm)
EC Design Certificate No and Expiration Date:	Certificate No: CE 595439 Expiration Date: 23 Feb 2023
Annex II, Clause 3 Certificate No and Expiration Date:	Certificate No: CE 590631 Expiration Date: 23 Feb 2023
Applicable Quality System Standards:	ISO 13485
Notified Body:	BSI Kitemark Court Knowlhill Milton Keynes MK5 8PP UK
Notified Body Number:	0086

Signature:

Lisa Becker
Senior Director, Regulatory Affairs

21 Feb 18
Issue Date

bsi.

By Royal Charter

EC Design-Examination Certificate

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

No. **CE 595439**

Issued To: **AGA Medical Corporation**
5050 Nathan Lane North
Plymouth
Minnesota
55442
USA

In respect of:

AMPLATZER Sizing Balloon II

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2013-02-24** Date: **2018-01-10** Expiry Date: **2023-02-23**

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Finished Product Number	Balloon Diameter (mm)	Volume at Diameter (cc)	Useable Balloon Length (mm)	Catheter Useable Length (cm)	Shaft French Size (F)	Maximum Recommended Inflation Volume (cc)	Minimum Volume at Failure (cc)
9-SB-018	18	10	35	70	6	12	25
9-SB-024	24	25	45	70	7	25	60
9-SB-034	34	55	55	70	8	90	120

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Certificate History

Date	Reference Number	Action
24 February 2013	10139846	First Issue – Transfer from another Notified Body.
25 August 2015	10156926	DuPont Tyvek Medical Transition Project update.
01 February 2016	10160623	Addition of Sterigenics Willowbrook, IL as a sterilizer.
Current	8864699	Certificate renewal.

First Issued: **2013-02-24** Date: **2018-01-10** Expiry Date: **2023-02-23**

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