

AMPLATZER™ GUIDEWIRES

Ordering Information

Contents: 1 guidewire

Model/ Reorder No	Diam (in)	Body	Floppy Tip Lgth (cms)	Tip Description	Usable Lgth (cm)
9-GW-001	0.035	Super Stiff	6	7.5 mm, Modified J-tip	260
9-GW-002	0.035	Super Stiff	5	1.5 mm, Modified J-tip	260
9-GW-003	0.035	Super Stiff	20	6 mm, J-tip	300
9-GW-004*	0.035	Soft Tip, Fixed Core	NA	6 mm, J-tip	300

*9-GW-004, also referred to as “Noodlewire,” is a soft tip, flexible guidewire recommended for establishing an arterial-venous loop, facilitating closure of ventricular septal defects.

Amplatzer™ Guidewire

Guidewire

es: Guia
pt: Fio-Guia
tr: Kilavuz Teli

UDI



(01)00811806010724(17)261231(10)9941803



2026-12-31

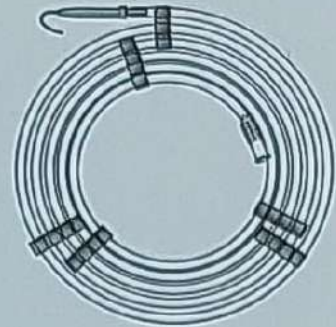
REF

9-GW-002



LOT

9941803



	0.035/0.889
	260 cm
	1.5 mm MOD J
	PTFE
	FIXED



STERILE EO



Does not contain
natural rubber
latex components



2022-01-24

CE
2797



Abbott Medical
5050 Nathan Lane North
Plymouth, MN
55442 USA
+1 855 478 5833
+1 651 756 5833

EC REP

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

Manufactured By

Lake Region Medical Limited,
Butlersland, New Ross, Co.
Wexford, Ireland.

Made in Ireland



AGABF-031V

600035212 B

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



Issue Date

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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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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-LLLLT 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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Page 2 of 3

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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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Page 3 of 3

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