EC Design-Examination Certificate

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

No. **CE 649387**

Issued To: **Argon Medical Devices, Inc.**
1445 Flat Creek Road
Athens
Texas
75751
USA

In respect of:

Option ELITE Vena Cava Filter System

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: **2016-06-09** Date: **2020-04-16** Expiry Date: **2024-02-16**

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Option Elite Retrievable Vena Cava Filter

Classification: class III
Intended purpose per IFU

The Option ELITE Filter is indicated for the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the inferior vena cava (IVC) in the following conditions:
- Pulmonary thromboembolism when anticoagulants are contraindicated
- Failure of anticoagulant therapy in thromboembolic disease
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated

The Option ELITE Filter may be removed according to the instructions supplied in the IFU, entitled "Optional Procedure for Filter Retrieval" in patients who no longer require a filter. Retrieval of the filter can only be performed by the jugular approach.

The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when used in conjunction with the delivery of radiopaque contrast media to the vena cava.

Catalog Number	System
352506070E	Option Elite Retrievable Vena Cava Filter System
352506100E	Option Elite 100cm Retrievable Vena Cava Filter System

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Certificate History

Date	Reference Number	Action
09 June 2016	10161337	First issue. Devices previously certified by another Notified Body.
28 April 2017	10165980	Supplemental review of 100cm data.
19 February 2019	7780687	Traceable to NB 0086.
14 June 2019	9635466	Certificate renewal.
Current	3099198	Manufacturing transfer from Merit Medical (Malvern, PA) to Argon Medical (Athens, TX) and Sterilization move to Sterigenics (Grand Prairie, TX). Added Classification and Intended Purpose per IFU.

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