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):

Albert Roossien, Regulatory Lead

First Issued: **2016-06-09** Date: **2019-02-19** Expiry Date: **2019-02-16**

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Supplementary Information to CE 649387

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Option Elite Retrievable Vena Cava Filter

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

First Issued: **2016-06-09** Date: **2019-02-19** Expiry Date: **2019-02-16**

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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.
Current	7780687	Traceable to NB 0086.

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