By Royal Charter

EC Design-Examination Certificate

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

No. **CE 649387**

Issued To: **Argon Medical Devices, Inc.**
also trading as Becton Dickinson
Infusion Therapy Systems 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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **09 June 2016** Date: **09 June 2016** Expiry Date: **16 February 2019**

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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: **09 June 2016** Date: **09 June 2016** Expiry Date: **16 February 2019**

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Certificate History

Date	Reference Number	Action
09 June 2016	10161337	First issue. Devices previously certified by another Notified Body.

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