

# 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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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.

# EC Design-Examination Certificate

## Supplementary Information to CE 649387

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**USA**

## 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

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## Certificate History

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

First Issued: **09 June 2016**

Date: **09 June 2016**

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