

# EC Design-Examination Certificate

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

**No.****CE 577360**

Issued To:

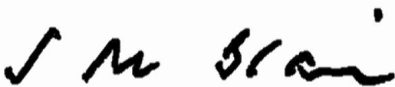
**Argon Medical Devices, Inc.  
1445 Flat Creek Road  
Athens  
Texas  
75751  
USA**

In respect of:

**First PICC Catheter**

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):



Stewart Brain, Head of Compliance & Risk -  
Medical Devices

First Issued: **2012-01-30**Date: **2017-09-18**Expiry Date: **2022-01-29**

...making excellence a habit.™

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.

# EC Design-Examination Certificate

## Supplementary Information to CE 577360

Issued To:

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

### **First PICC™ Catheter**

#### **Single Lumen Catheters**

384101, 384232, 384156, 384157, 384158

#### **Dual Lumen Catheters**

384159

First Issued: **2012-01-30**Date: **2017-09-18**Expiry Date: **2022-01-29**

...making excellence a habit.™

Page 2 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.

# EC Design-Examination Certificate

## Supplementary Information to CE 577360

Issued To:

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

## Certificate History

Date	Reference Number	Action
30 January 2012	10129835	First issue (based on CE 52793).
23 November 2015	10159122	Addition of the Sterigenics location in Grand Prairie, TX as a sterilization location.
24 September 2016	10164659	Change affecting Tyvek® 1073B and Tyvek® 1059B packaging materials. All product codes are affected.
09 January 2017	10166571	Renewal.
Current	8762748	Change on packaging tray design and packaging process.

First Issued: **2012-01-30**

Date: **2017-09-18**

Expiry Date: **2022-01-29**

...making excellence a habit.™

Page 3 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.