By Royal Charter

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**

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Supplementary Information to CE 577360

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First PICC™ Catheter

Single Lumen Catheters

384101, 384232, 384156, 384157, 384158

Dual Lumen Catheters

384159

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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**

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