

EC Design-Examination Certificate

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

No.**CE 577360**

Issued To:

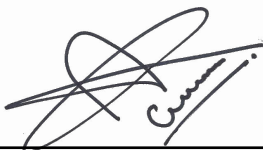
**Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens
Texas
75751
USA**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2012-01-30**Date: **2019-02-19**Expiry Date: **2022-01-29**

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Supplementary Information to CE 577360

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1445 Flat Creek Road
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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.
18 September 2017	8762748	Change on packaging tray design and packaging process.
Current	7780687	Traceable to NB 0086.

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