

EC Design-Examination Certificate

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

No.**CE 589347**

Issued To:

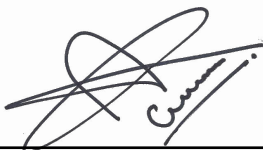
**Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens
Texas
75751
USA**

In respect of:

L-Cath™ Peripherally Inserted Central Catheters

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: **2013-01-24**Date: **2019-02-19**Expiry Date: **2023-01-23**

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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 589347

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L-Cath™ PICC (Peripherally Inserted Central Catheter)

Catalog Number	Description	Size
384463	PICC Polyurethane Single Lumen	20G (3Fr) x 60cm
384464	PICC Polyurethane Single Lumen	18G (3.5Fr) x 60cm
384465	PICC Polyurethane Single Lumen	16G (5Fr) x 60cm
384466	PICC Polyurethane Dual Lumen	20G (2.6Fr) x 60cm
384467	PICC Polyurethane Dual Lumen	18G (3.5Fr) x 60cm
384468	PICC Polyurethane Dual Lumen	16G (5Fr) x 60cm
384539	PICC Polyurethane Single Lumen	26G (1.9Fr) x 30cm
384540	PICC Polyurethane Single Lumen	28G (1.2Fr) x 25cm

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Certificate History

Date	Reference Number	Action
24 January 2013	10136373	First issue.
23 November 2015	10159122	Addition of the Sterigenics location in Grand Prairie, TX as a sterilization location.
18 September 2017	8762748	Change on packaging tray design and packaging process.
09 February 2018	8845742	Certificate Renewal.
Current	7780687	Traceable to NB 0086.

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