

# EC Design-Examination Certificate

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

**No.****CE 584996**

Issued To:

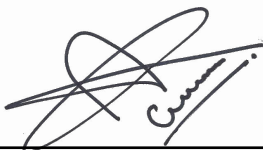
**Argon Medical Devices, Inc.  
1445 Flat Creek Road  
Athens  
Texas  
75751  
USA**

In respect of:

**UltraStream Chronic Dialysis Catheter Kit**

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: **2012-08-03**Date: **2019-02-19**Expiry Date: **2022-08-02**

...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.

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.

# EC Design-Examination Certificate

## Supplementary Information to CE 584996

Issued To:

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

### UltraStream Chronic Dialysis Catheter Kits

Component	Description
32001524	Exchange Kit 15.5F x 24cm
32001528	Exchange Kit 15.5F x 28cm
32001532	Exchange Kit 15.5F x 32cm
32001536	Exchange Kit 15.5F x 36cm
32001540	Exchange Kit 15.5F x 40cm
32101524	Standard Kit 15.5F x 24cm
32101528	Standard Kit 15.5F x 28cm
32101532	Standard Kit 15.5F x 32cm
32101536	Standard Kit 15.5F x 36cm
32101540	Standard Kit 15.5F x 40cm
32401524	Peel Away Kit 15.5F x 24cm
32401528	Peel Away Kit 15.5F x 28cm
32401532	Peel Away Kit 15.5F x 32cm
32401536	Peel Away Kit 15.5F x 36cm
32401540	Peel Away Kit 15.5F x 40cm

First Issued: **2012-08-03**

Date: **2019-02-19**

Expiry Date: **2022-08-02**

...making excellence a habit.™

# EC Design-Examination Certificate

## Supplementary Information to CE 584996

Issued To:

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

## Certificate History

Date	Reference Number	Action
03 August 2012	10134043	First issue.
23 November 2015	10159122	Addition of the Sterigenics location in Grand Prairie, TX as a sterilization location.
03 August 2017	10171370	Certificate renewal.
Current	7780687	Traceable to NB 0086.

First Issued: **2012-08-03**

Date: **2019-02-19**

Expiry Date: **2022-08-02**

...making excellence a habit.™

Page 3 of 3

Validity of this certificate is conditional on the quality system of the notified body remaining effective as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound to the certificate holder's account.