

EC Design-Examination Certificate

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

No.**CE 565720**

Issued To:

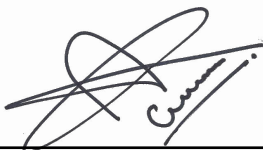
**Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens
Texas
75751
USA**

In respect of:

Endomyocardial Biopsy Forceps

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: **2011-02-28**Date: **2019-02-19**Expiry Date: **2022-12-01**

...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 565720

Issued To:

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

Product: Endomyocardial Forceps

Code	Product description
190020	Forceps, BIO/50/2.4/7.5F/STR/SS 05/1999
190030	Forceps, BIO/50/2.4/7.5F/PRE/FEB 05/1999
190031	Forceps, BIO/50/2.4/7.5F/MCURVE 05/1999
190040	Forceps, BIO/2.4/STR/SS/7.5F 05/1999
190051	Forceps, BIOPSY/50/1.8/MCURVE/FEP/5.5F 05/1999
190060	Forceps, BIOPSY/50/1.8/STR/SS/5.5F 05/1999
190065	Forceps, BIO/50/1.8/STR/SS/5.5F 05/1999
190066	Forceps, BIO/70/1.8/STR/FEP/5.5F 05/1999
190070	Forceps, BIOPSY/105/1.8/STR/SS/5.5F 05/1999
190075	Forceps, BIO/105/1.8/STR/SS/5.5F 05/1999
190080	Forceps, BIO/50/2.2/PRE/FEP/7F 05/1999
190081	Forceps, BIO/50/2.2/MCURVE/FEP/7F 05/1999
190085	Forceps, BIO/105/2.2/7F/STR/SS 05/1999
190086	Forceps, BIO/105/2.2/7F/STR/FEB 05/1999
190090	Forceps, BIO/50/1.5/5F/STR/SS 05/1999
190095	Forceps, BIO/105/1.5/5F/STR/SS 05/1999

First Issued: **2011-02-28**

Date: **2019-02-19**

Expiry Date: **2022-12-01**

...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.

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 565720

Issued To:

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

Certificate History

Date	Reference Number	Action
28 February 2011	10118187	First Issue - Transfer from another Notified Body.
03 December 2012	10137337	Certificate renewal.
23 November 2015	10159122	Addition of the Sterigenics location in Grand Prairie, TX as a sterilization location.
24 January 2018	8847348	Certificate renewal. Removal of product code 190061.
Current	7780687	Traceable to NB 0086.

First Issued: **2011-02-28**

Date: **2019-02-19**

Expiry Date: **2022-12-01**

...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.

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.