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EC Certificate - Full Quality Assurance System

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

No. **CE 565719**

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

In respect of:

The design and manufacture of single use instruments, catheters and access devices for intravascular and non-vascular applications, biopsy devices, fluid administration devices, thrombectomy devices, vena cava filter systems and hemodialysis catheters.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2011-02-28** Date: **2020-04-22** Expiry Date: **2022-12-01**

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Supplementary Information to CE 565719

Issued To:

Argon Medical Devices, Inc.
1445 Flat Creek Road
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Number	Device Name or Generic Device Group	Intended purpose per IFU
Class III		
---	Endomyocardial Biopsy Forceps	See CE 565720
---	Stainless Steel and PTFE-Coated Stainless Steel Guidewires	See CE 565721
---	First PICC Catheter	See CE 577360
---	UltraStream Chronic Dialysis Catheter Kit	See CE 584996
---	L-Cath Peripherally Inserted Central Catheters (PICC)	See CE 589347
---	Axcess Introducer with Multi-Purpose Curve Tip	See CE 602665
---	Atrieve Vascular Snare Kit	See CE 608298
---	Worker Guidewires	See CE 608299
---	Option Elite Vena Cava Filter System	See CE 649387

First Issued: **2011-02-28** Date: **2020-04-22** Expiry Date: **2022-12-01**

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Number	Device Name or Generic Device Group	Intended purpose per IFU
Class IIb		
MD0204	PE Drainage Catheters	General note: The Drainage Catheter product family is intended for utilization in general drainage (i.e., drainage of cysts, abscesses, haematomas, pleural exudates, pleuracenteses, paracenteses, ascites, gall bladders and nephrostomies), and biliary drainage applications.
		The Multipurpose Drainage Catheters and Sets are single-use devices intended for percutaneous drainage in a variety of drainage applications (e.g., nephrostomy, biliary and access), either by direct stick or Seldinger access technique. Surgical drains are used to decompress or drain either fluid or air from the area of surgery to prevent the accumulation of fluid or air.
MD0204	SKATER Drainage Catheters	The product is for single step drainage of cysts, abscesses, heamatomaes, pleural exudates, ascites, gall bladders and nephrostomies. The product is for single step drainage of cysts, gall bladders and nephrostomies. The product is for drainage of cysts, abscesses, haematomas, pleural exudates, ascites, gall bladders and nephrostomies. The product is for drainage of cysts, gall bladders and abscesses The product is for biliary drainage The product is for nephrostomies The product is for drainage using Seldinger technique

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Number	Device Name or Generic Device Group	Intended purpose per IFU
Class IIb		
MD1104	Cleaner Rotational Thrombectomy Device	General note: Cleaner rotational thrombectomy device is for general thrombectomy in the peripheral vasculature The Cleaner 15 Rotational Thrombectomy System is intended for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis grafts; mechanical declotting and controlled and selective infusion of physician-specified fluids, including thrombolytics in the peripheral vasculature. The CLEANER 15™ Rotational Thrombectomy System is indicated for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts The CLEANER XT™ Rotational Thrombectomy System is indicated for mechanical declotting and controlled and selective infusion of physician specified fluids, including thrombolytics, in the peripheral vasculature. The CLEANER XT™ Rotational Thrombectomy System is indicated for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts.

First Issued: **2011-02-28** Date: **2020-04-22** Expiry Date: **2022-12-01**

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Number	Device Name or Generic Device Group	Intended purpose per IFU
Class IIa		
MD0106	Access Devices	---
MD0102	Fluid Management Devices	
MD0106	Biopsy Devices	
Class Is		
MD0102	HSG Catheters	---
MD0102	Galactography	
MD0102	Lorad Needle Guide	
MD0102	Drainage Bag	
MD0102	Connecting Tubes	
MD0106	Skin Fix	
MD0106	Equipment Covers	
MD0102	Locking Syringe	

First Issued: **2011-02-28** Date: **2020-04-22** Expiry Date: **2022-12-01**

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EC Design-Examination Certificate

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

No. **CE 608298**

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

In respect of:

Atrieve™ Vascular Snare 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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-02-28** Date: **2019-06-27** Expiry Date: **2024-02-27**

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EC Design-Examination Certificate

Supplementary Information to CE 608298

Issued To:

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

Product: Atrieve™ Vascular Snare Kit

Product Code	Diameters (mm)	Working Diameter (mm)	Snare Length (cm)	Shaft Diameter (in)	Delivery Catheter Size (Fr)	Delivery Catheter Length (cm)	Delivery Catheter Inside Diameter (in)
381003004	4	2-4	175	0.018	3.2	150	0.030
381003008	8	4-8	175	0.018	3.2	150	0.030
382006010	10	6-10	120	0.026	6	100	0.062
382006015	15	9-15	120	0.026	6	100	0.062
382006020	20	12-20	120	0.026	6	100	0.062
382007030	30	18-30	120	0.026	7	100	0.074
382007045	45	27-45	120	0.026	7	100	0.074

First Issued: **2014-02-28** Date: **2019-06-27** Expiry Date: **2024-02-27**

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EC Design-Examination Certificate

Supplementary Information to CE 608298

Issued To:

Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens
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Certificate History

Date	Reference Number	Action
28 February 2014	10144761	First Issue.
08 June 2018	8938885	Removal of reference to Becton Dickinson Infusion Therapy Systems Inc. from certificate address.
19 February 2019	7780687	Traceable to NB 0086
Current	9665677	Certificate Renewal.

First Issued: **2014-02-28** Date: **2019-06-27** Expiry Date: **2024-02-27**

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ARGON
MEDICAL DEVICES

Declaration of Conformity

for

Atrieve™ Vascular Snare Kit

Catalog No.	Product Name
382006010	Atrieve Vascular Snare ™Kit, 6-10 mm diameter x 120 cm snare, 6F x 100 cm catheter
382006015	Atrieve Vascular Snare ™Kit, 9-15 mm diameter x 120 cm snare, 6F x 100 cm catheter
382006020	Atrieve Vascular Snare ™Kit, 12-20 mm diameter x 120 cm snare, 6F x 100 cm catheter
382007030	Atrieve Vascular Snare ™Kit, 18-30 mm diameter x 120 cm snare, 7F x 100 cm catheter
382007045	Atrieve Vascular Snare ™Kit, 27-45 mm diameter x 120 cm snare, 7F x 100 cm catheter
381003004	Atrieve Vascular Snare ™Kit, 2-4 mm diameter x 175 cm snare, 3.2F x 150 cm catheter
381003008	Atrieve Vascular Snare ™Kit, 4-8 mm diameter x 175 cm snare, 3.2F x 150 cm catheter

Product Classification: **Class III**
Annex IX, Rule **6** of MDD 93/42/EEC

Conformity Assessment Route: **Full Quality Assurance**
Annex II, excluding Section 4, of MDD 93/42/EEC

Design Examination
Annex II Section 4 of MDD 93/42/EEC

EC Certificate(s): CE Marking of Conformity Certificate No.: *CE 565719*
Design Examination Certificate No.: CE 608298

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

Authorized Representative:
Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Notified Body:
BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Identification No.: 2797

We herewith declare under our sole responsibility that the products under this declaration are in conformity with the European Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC). This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the Medical Devices Directive. The conformity to the Full Quality Assurance System and the design examination of the product under this declaration are described in the aforementioned EC Certificates issued and delivered by BSI.

Approved By: Rebecca L Ellis — 28 Feb 2019

Rebecca L. Ellis — **Date**
Vice President of RA and QA

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate No: **FM 700791**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture and contract manufacturing and distribution of sterile and non-sterile disposable and reusable medical devices consisting of single and multi-lumen central venous catheterization, endovascular snares, drainage catheters and collection devices, hystero-salpingography catheters, dialysis catheters, fluid management systems, IV lines, manifolds, prostate seeding needles and stabilization devices, biopsy and access needles, breast biopsy site markers, syringes, hemostatic wound dressing, guidewires, biopsy instruments and tray, introducer kits, trays and accessories, scalpels, arterial line kits, procedure drapes, equipment covers, high pressure lines, monitoring lines, stopcocks, adapters and plugs, vascular and non-vascular care products for cardiology, interventional radiology and critical care procedures, thrombectomy devices and vena cava filter systems.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2010-09-03
Latest Revision Date: 2019-08-14

Effective Date: 2019-04-29
Expiry Date: 2022-04-28

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