



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, Senior Vice President Medical Devices

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

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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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.



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Supplementary Information to CE 565719

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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 |
| --- | Access 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 |

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| 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 | <p>The product is for single step drainage of cysts, abscesses, haematomaes, pleural exudates, ascites, gall bladders and nephrostomies.</p> <p>The product is for single step drainage of cysts, gall bladders and nephrostomies.</p> <p>The product is for drainage of cysts, abscesses, haematomas, pleural exudates, ascites, gall bladders and nephrostomies.</p> <p>The product is for drainage of cysts, gall bladders and abscesses The product is for biliary drainage</p> <p>The product is for nephrostomies</p> <p>The product is for drainage using Seldinger technique</p> |

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| Class IIb | | |
| MD1104 | Cleaner Rotational Thrombectomy Device | <p>General note: Cleaner rotational thrombectomy device is for general thrombectomy in the peripheral vasculature</p> <p>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.</p> <p>The CLEANER 15™ Rotational Thrombectomy System is indicated for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts</p> <p>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.</p> <p>The CLEANER XT™ Rotational Thrombectomy System is indicated for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts.</p> |

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| 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 | |

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