By Royal Charter

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: **2021-02-25** Expiry Date: **2024-05-26**

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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
---	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

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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. The SKATER™ All-Purpose and Nephrostomy Drainage Set is used for fluid drainage procedures.

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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.

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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	

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Date	Reference Number	Action
28 February 2011	7561304	First Issue - Transfer from another Notified Body.
11 October 2011	7752883	"Also trading as Becton Dickinson Infusion Therapy Systems Inc." added to the manufacture name. Becton Dickinson Infusion Therapy Systems, Inc. S.A. de C.V., Becton Dickinson Infusion Therapy Systems, Inc., Argon Critical Care Systems Singapore Pte. Ltd. and B.Braun Medical Inc. added to the list of significant subcontractors.
25 January 2012	7791401	3M Health Care, Aspen Surgical Products, Medron, Greatbatch Medical and Martech Medical Products added to the list of significant subcontractors.
03 August 2012	7807038	Rex Medical, Aspen Surgical Puerto Rico and Halkey-Roberts added to the list of significant subcontractors.
31 October 2012	7842537	Certificate Renewal. Address change for Ningbo Shengyurui Medical Appliances and M/s Ribbel International.
19 February 2014	8108569	Scope extension to include biopsy devices and access devices for non-vascular applications. List of subcontractors updated to include the significant suppliers involved in the manufacturing of the new products.

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Date	Reference Number	Action
30 April 2015	8283853	Removal of the following significant subcontractors: Becton & Dickinson Infusion Therapy USA; Becton & Dickinson Infusion Therapy Mexico; Shanghai Greenway Medical Apparatus; Ningbo Shengyuri Medical Applications; Medron Inc.; Greatbatch Medical; B.Braun Medical Inc.; M/s Ribbel International ltd; Martech Medical Products; Aspen Surgical Michgan, Aspen Surgical Puerto Rico; 3M Healthcare; Wenzhou KLF Medical Plastics. Amendment to the address of Rex Medical L.P. Amendment to the name of Manan Medical Products Inc. Changed Manan and Pelham Plastics to crucial supplier. Addition of Control of Sterilization to the services supplied by Manan. Minor correction to the address of Manan.
09 June 2016	8481407	Extension of the scope to include thrombectomy devices, vena cava filter systems and hemodialysis catheters. Add the significant subcontractors NDC, Merit Medical Systems, and Precision Medical Products. Remove Rex Medical as a significant subcontractor. STERIS Isomedix Services subcontractor removed.
28 April 2017	8710335	Remove also trading as Becton Dickinson from the address. Update EU Representative address.

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Date	Reference Number	Action
27 November 2017	8849506	Certificate Renewal. Change the name of subcontractor Argon Critical Care Systems to Merit Medical Singapore Pte. Ltd. Change the name of subcontractor Accellent, Inc. to Lake Region Medical. Update the address for subcontractor Nitinol Device Components. Remove pressure monitoring from the scope as Argon Medical is no longer the legal manufacturer of these devices.
19 February 2019	7780687	Traceable to NB 0086.
22 April 2020	3150714	Remove Merit Medical System, Inc. Malvern PA and Singapore as subcontractor; Update subcontractor names to Viant AS&O, Argon Medical Devices, and Roechling Medical Lancaster; Added Products Table in supplementary information section.
25 February 2021	3310149	Certificate Renewal. Remove Synergy Health AST, LLC as Subcontractor. Update to SKATER Intended Use in product table. Removal of Class Is devices from the certificate as they are covered by Annex V certificate. Administrative correction to the EU Representative address.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		

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Date	Reference Number	Action
29 February 2024	30114135	Change of EU Authorised Representative address to Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.

Inspiring trust for a more resilient world.

29 February 2024

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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 565719	93/42/EEC Annex II excluding Section 4	30114135	Change of EU Authorised Representative address to Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices