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

Digitally signed by Kojevnikov Dmitrii
Date: 2020.11.06 12:50:26 EET
Reason: MoldSign Signature
Location: Moldova

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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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

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	**Service(s) supplied**
Argon Medical Devices, Inc. 241 W. Palatine Road Wheeling Illinois 60090 USA	**Control of Sterilization** **Crucial Supplier**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Lemco Enterprises P.O. Box 1407 3204 Hale Road Ardmore Oklahoma 73402 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Nitinol Devices & Components Costa Rica, S. R. L. Coyol Free Zone Buildings B14, B15, and B25 El Coyol, Alajuela 20102 Costa Rica	**Manufacture**
Pelham Plastics Inc 42 Dick Tracy Drive Pelham New Hampshire 03076 USA	**Crucial Supplier**
Roechling Medical Lancaster, LLC 44 Denver Road Denver PA 17517 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	**ETO Sterilization**
Synergy Health AST, LLC 500 West 4th Street Lima Ohio 45804 USA	**Radiation (E Beam Sterilization)**
Viant AS&O, LLC a.t.a. (formerly) Lake Region Medical 45 Lexington Drive Laconia New Hampshire 03246 USA	**Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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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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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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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.
Current	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.