

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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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.

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Supplementary Information to CE 565719

Issued To:

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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
---	Axxess 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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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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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	<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.</p> <p>The product is for biliary drainage.</p> <p>The product is for nephrostomies.</p> <p>The product is for drainage using Seldinger technique.</p> <p>The SKATER™ All-Purpose and Nephrostomy Drainage Set is used for fluid drainage procedures.</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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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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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, Inc. 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

Viant AS&O, LLC a.t.a. (formerly) Lake Region Medical
 45 Lexington Drive
 Laconia
 New Hampshire 03246
 USA

Manufacture

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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 Michigan, 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.
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.
Current	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.

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