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):

Albert Roossien, Regulatory Lead

First Issued: **2011-02-28** Date: **2019-02-19** Expiry Date: **2022-12-01**

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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:

Certificate No:	**CE 565719**
Date:	**2019-02-19**
Issued To:	**Argon Medical Devices, Inc.** **1445 Flat Creek Road** **Athens** **Texas** **75751** **USA**

Subcontractor:	**Service(s) supplied**
EMERGO EUROPE Prinsessegracht 20 2514 AP, The Hague The Netherlands	**EU Representative**
Lake Region Medical 45 Lexington Laconia New Hampshire 03246 USA	**Manufacture**
Lemco Enterprises P.O. Box 1407 3204 Hale Road Ardmore Oklahoma 73402 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Manan Medical Products Inc 241 W. Palatine Road Wheeling Illinois 60090 USA	**Control of Sterilization** **Crucial Supplier**
Merit Medical Singapore Pte. Ltd. 198 Yishun Avenue 7 Singapore 768926 Singapore	**ETO Sterilization** **Manufacture** **Packaging**
Merit Medical Systems, Inc. 65 Great Valley Parkway Malvern PA 19355 USA	**Manufacture**

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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**
Precision Medical Products, Inc. 44 Denver Road P.O. Box 300 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 OH 45804 USA	**E Beam Sterilization**

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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.
Current	7780687	Traceable to NB 0086.