By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 566724**

Issued To: **Argon Medical Devices, Inc.**
1445 Flat Creek Road
Athens
Texas
75751
USA

In respect of:

Those aspects of Annex V related to sterility in the manufacture of accessories to surgical instruments and accessories to catheters, drainage and biopsy devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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: **2021-02-24** Expiry Date: **2024-05-26**

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Supplementary Information to CE 566724

Issued To:

Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens
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Number	Device Name or Generic Device Group	Intended purpose per IFU
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	

First Issued: **2011-02-28** Date: **2021-02-24** Expiry Date: **2024-05-26**

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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 566724**
Date:	**2021-02-24**
Issued To:	**Argon Medical Devices, Inc.** **1445 Flat Creek Road** **Athens** **Texas** **75751** **USA**

Subcontractor:	**Service(s) supplied**
Ambu Sdn/BHd. (336938-A) Lot 69-B, Lintang Bayan, Lepas 6, 11900 Penang, Malaysia (Supplied through Ambu, Inc. 3740 Baymeadow Dr, Glen Burnie MD21060) USA	**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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Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 566724**
Date:	**2021-02-24**
Issued To:	**Argon Medical Devices, Inc.** **1445 Flat Creek Road** **Athens** **Texas** **75751** **USA**

Subcontractor:	**Service(s) supplied**
Lina Medical APS Formervangen 5 Glostrup 2600 Denmark	**Control of Sterilization** **Manufacture**
Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	**ETO Sterilization**
Unomedical s.r.o. Priemyselny Park 3 07101 Michalovce Slovakia	**Control of Sterilization** **Manufacture**

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bsi.

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 566724**

Date: **2021-02-24**

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Date	Reference Number	Action
28 February 2011	7581777	First Issue – Transfer from another Notified Body.
31 October 2012	7842540	Certificate Renewal.
19 February 2014	8108569	Scope extension to include drainage and biopsy devices. List of subcontractors updated to include the significant suppliers involved in the manufacturing of the new products.
30 April 2015	8283851	Ambu Sdn/BHd. added to the list as crucial supplier. Removal of Hangzhau Jincheng Medical as significant subcontractor.
28 April 2017	8710335	Remove also trading as Becton Dickinson from the address. Update EU Representative address. Removal of Steris Isomedix Services (29306, Spartanburg) from list of subcontractors.
27 November 2017	8849505	Certificate Renewal.
19 February 2019	7780687	Traceable to NB 0086.

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 566724**

Date: **2021-02-24**

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Date	Reference Number	Action
Current	3309766	Certificate Renewal. Addition of supplementary product table.