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:

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1445 Flat Creek Road
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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	

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EC Certificate - Production Quality Assurance Certificate History

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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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Date	Reference Number	Action
24 February 2021	3309766	Certificate Renewal. Addition of supplementary product table.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
04 April 2024	30113904	Change of EU Authorised Representative address to Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.

Inspiring trust for a more resilient world.

04 April 2024

Argon Medical Devices, Inc.
1445 Flat Creek Road
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75751
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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 566724	93/42/EEC Annex V	30113904	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