

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

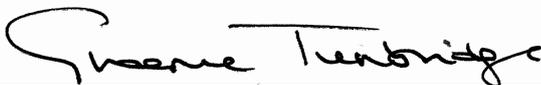
No. **UKCA 759758**
Issued To: **Argon Medical Devices, Inc.**
1445 Flat Creek Road
Athens
Texas
75751
USA

In respect of:

Design, manufacture and final inspection of sterile guidewires, access devices for intravascular and non-vascular applications, percutaneous drainage systems, angiography and hemodynamic devices, introducer sets and devices for administration, withdrawal and collection.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2024-06-17**

Date: **2025-12-18**

Expiry Date: **2029-05-23**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the regulation as demonstrated through the required surveillance activities of the Approved Body. This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to UKCA 759758

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Device code	Device Name	Intended purpose per IFU
Class III		
---	WORKER™ Guidewire (Standard, Amplatz and Bentson)	See UKCA 759760
---	Amplatz Guidewire	See UKCA 759760
---	Guidewires	See UKCA 759765
Class IIb		
MD 1104	Angiography and Haemodynamic Devices	---
MD 0204	Percutaneous Drainage Systems	---
Class IIa		
MD 0106	Access Devices	---
MD 0106	Introducer Sets	---
MD 0102	Devices for Administration, Withdrawal and Collection	---

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Certificate History

Certificate No: **UKCA 759758**
 Date: **2025-12-18**
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Date	Reference Number	Action
2024-06-17	3558906	First Issue; Traceable to MDR 744183.
Current	30606092	Extension of the certificate scope and addition to the device table of: Angiography and Haemodynamic Devices (class IIb), Percutaneous Drainage Systems (class IIb), Introducer Sets (class IIa); Devices for Administration, Withdrawal and Collection (class IIa).

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