

UKCA Design-Examination Certificate

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

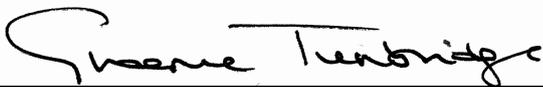
No. **UKCA 759760**
Issued To: **Argon Medical Devices, Inc.**
1445 Flat Creek Road
Athens
Texas
75751
USA

In respect of:

WORKER™ Guidewire (Standard, Amplatz and Bentson)

BSI has performed a design examination of the above devices in accordance with Part II of The Medical Devices Regulations 2002, Annex II Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The design conforms to the requirements of this regulation. For the placing on the market of these products an Annex II (modified as described above) excluding 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: **2025-12-03**

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.

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000
Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
A member of BSI Group of Companies.

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Supplementary Information to UKCA 759760

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Intended Purpose per IFU: Guidewires are intended to facilitate the percutaneous placement of intravascular and non-vascular devices during diagnostic and intervention procedures.

Classification: Class III

Catalogue Number	Device Name	Model, Type
110135080	WORKER™ Guidewires (Standard, Amplatz and Bentson)	WORKER™ Guidewire Standard Straight 0.035"/80cm/3.5cm
110135150		WORKER™ Guidewire Standard Straight 0.035"/150cm/3.5cm
110135180		WORKER™ Guidewire Standard Straight 0.035"/180cm/3.5cm
110535080		WORKER™ Guidewire Standard J Curve 0.035"/80cm/3.5cm
110535150		WORKER™ Guidewire Standard J Curve 0.035"/150cm/3.5cm
110535180		WORKER™ Guidewire Standard J Curve 0.035"/180cm/3.5cm
110535260		WORKER™ Guidewire Standard J Curve 0.035"/260cm/3.5cm
114035090		WORKER™ Guidewire Amplatz Straight 0.035"/90cm/7.5cm

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Catalogue Number	Device Name	Model, Type
114035150	WORKER™ Guidewires (Standard, Amplatz and Bentson)	WORKER™ Guidewire Amplatz Straight 0.035"/150cm/7.5cm
114035180		WORKER™ Guidewire Amplatz Straight 0.035"/180cm/7.5cm
114035260		WORKER™ Guidewire Amplatz Straight 0.035"/260cm/7.5cm
114135080		WORKER™ Guidewire Amplatz Straight 0.035"/80cm/3.5cm
114135150		WORKER™ Guidewire Amplatz Straight 0.035"/150cm/3.5cm
114135180		WORKER™ Guidewire Amplatz Straight 0.035"/180cm/3.5cm
114135260		WORKER™ Guidewire Amplatz Straight 0.035"/260cm/3.5cm
114235090		WORKER™ Guidewire Amplatz J Curve 0.035"/90cm/7.5cm
114235150		WORKER™ Guidewire Amplatz J Curve 0.035"/150cm/7.5cm

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Certificate History

Date	Reference Number	Action
2024-06-17	30110687	First Issue; Traceable to MDR 762338
2025-03-20	30253861	Introduction of a new sterilization cycle in an existing sterilization site.
Current	30495662	Removal of certain guidewire models from the device schedule, update of the certificate scope, and correction of a typo in the description of Catalogue Number 114235150.

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