By Royal Charter

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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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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