By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 762338 R000

Manufacturer: Argon Medical Devices, Inc.

Address:
1445 Flat Creek Road
Athens
Texas
75751
USA

Single Registration Number: US-MF-000002324

EU Authorised Representative: Emergo Europe B.V.

Address:
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-05-24**

Current Issue Date: **2025-12-03**

Starting Validity Date: **2025-12-03**

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

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Device Schedule:

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

Type (Codes as per (EU) 2017/2185): MDN 1203

Risk Classification: Class III

Device Name	Description	Model	Basic UDI-DI
WORKER™ Guidewire (Standard, Amplatz and Bentson)	WORKER™ Guidewire Standard Straight 0.035"/80cm/3.5cm	110135080	08863332700352V
	WORKER™ Guidewire Standard Straight 0.035"/150cm/3.5cm	110135150	
	WORKER™ Guidewire Standard Straight 0.035"/180cm/3.5cm	110135180	
	WORKER™ Guidewire Standard J Curve 0.035"/80cm/3.5cm	110535080	08863332700342T
	WORKER™ Guidewire Standard J Curve 0.035"/150cm/3.5cm	110535150	
	WORKER™ Guidewire Standard J Curve 0.035"/180cm/3.5cm	110535180	
	WORKER™ Guidewire Standard J Curve 0.035"/260cm/3.5cm	110535260	

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Device Name	Description	Model	Basic UDI-DI
WORKER™ Guidewire (Standard, Amplatz and Bentson)	WORKER™ Guidewire Amplatz Straight 0.035"/90cm/7.5cm	114035090	08863332700332R
	WORKER™ Guidewire Amplatz Straight 0.035"/150cm/7.5cm	114035150	
	WORKER™ Guidewire Amplatz Straight 0.035"/180cm/7.5cm	114035180	
	WORKER™ Guidewire Amplatz Straight 0.035"/260cm/7.5cm	114035260	
	WORKER™ Guidewire Amplatz Straight 0.035"/80cm/3.5cm	114135080	
	WORKER™ Guidewire Amplatz Straight 0.035"/150cm/3.5cm	114135150	
	WORKER™ Guidewire Amplatz Straight 0.035"/180cm/3.5cm	114135180	
	WORKER™ Guidewire Amplatz Straight 0.035"/260cm/3.5cm	114135260	

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Device Name	Description	Model	Basic UDI-DI
WORKER™ Guidewire (Standard, Amplatz and Bentson)	WORKER™ Guidewire Amplatz J Curve 0.035"/90cm/7.5cm	114235090	08863332700322P
	WORKER™ Guidewire Amplatz J Curve 0.035"/150cm/7.5cm	114235150	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-05-24	3582036	Issued
2025-03-20	30253871	Amended – Introduction of a new sterilization cycle in an existing sterilization site.
Current	30495639	Restricted – Removal of certain guidewire models from the device schedule.

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

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