

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]

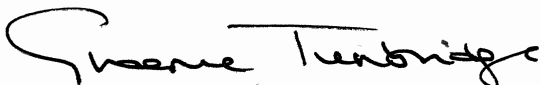
No. UKCA 759760
Issued To: **Argon Medical Devices, Inc.**
1445 Flat Creek Road
Athens
Texas
75751
USA

In respect of:

WORKER™ Guidewire (Standard, Amplatz and Bentson) and Amplatz Guidewire

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: **2024-06-17**

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

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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 |
| 110138150 | | WORKER™ Guidewire Standard Straight 0.038"/150cm/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 |
| 110538150 | | WORKER™ Guidewire Standard J Curve 0.038"/150cm/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 Straight 0.035"/150cm/7.5cm |
| 116035180 | | WORKER™ Guidewire Bentson type 0.035"/180cm/15cm |

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| Catalogue Number | Device Name | Model, Type |
|------------------|-------------------|---|
| G61135090 | Amplatz Guidewire | Amplatz Straight Guidewire 0.035"/90cm/7.5cm (Mermaid Medical) |
| G61135150 | | Amplatz Straight Guidewire 0.035"/150cm/7.5cm (Mermaid Medical) |
| G61135180 | | Amplatz Straight Guidewire 0.035"/180cm/7.5cm (Mermaid Medical) |
| G61135260 | | Amplatz Straight Guidewire 0.035"/260cm/7.5cm (Mermaid Medical) |
| G61235080 | | Amplatz Straight Guidewire 0.035"/80cm/3.5cm (Mermaid Medical) |
| G61235150 | | Amplatz Straight Guidewire 0.035"/150cm/3.5cm (Mermaid Medical) |
| G61235180 | | Amplatz Straight Guidewire 0.035"/180cm/3.5cm (Mermaid Medical) |
| G61235260 | | Amplatz Straight Guidewire 0.035"/260cm/3.5cm (Mermaid Medical) |
| G61335090 | | Amplatz J Curve Guidewire 0.035"/90cm/7.5cm (Mermaid Medical) |

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Certificate History

| Date | Reference Number | Action |
|---------|------------------|--------------------------------------|
| Current | 30110687 | First Issue; Traceable to MDR 762338 |



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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 389 Chiswick High Road, London, W4 4AL, UK.
A member of BSI Group of Companies.