

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No.**CE 608299**

Issued To:

**Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens
Texas
75751
USA**

In respect of:

WORKER™ Guidewires

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-03-31**Date: **2019-07-19**Expiry Date: **2024-03-30**

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Page 1 of 5

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive 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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Supplementary Information to CE 608299

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Catalogue Number	Device Name	Specifications	Intended purpose per IFU	Classification
110135080	WORKER™ Standard Straight	0.035" x 80 cm, 3.5 cm soft tip	The intended use of Worker Guidewires is for use in facilitating the placement of catheters within the coronary and peripheral vasculature. They are also for use in the placement of non-vascular catheters.	Class III
110135150	WORKER™ Standard Straight	0.035" x 150 cm, 3.5 cm soft tip		Class III
110135180	WORKER™ Standard Straight	0.035" x 180 cm, 3.5 cm soft tip		Class III
110138150	WORKER™ Standard Straight	0.038" x 150 cm, 3.5 cm soft tip		Class III
110535080	WORKER™ Standard J Curve	0.035" x 80 cm, 3 mm J, 3.5 cm soft tip		Class III
110535150	WORKER™ Standard J Curve	0.035" x 150 cm, 3 mm J, 3.5 cm soft tip		Class III
110535180	WORKER™ Standard J Curve	0.035" x 180 cm, 3 mm J, 3.5 cm soft tip		Class III

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Page 2 of 5

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Catalogue Number	Device Name	Specifications	Intended purpose per IFU	Classification
110535260	WORKER™ Standard J Curve	0.035" x 260 cm, 3 mm J, 3.5 cm soft tip	The intended use of Worker Guidewires is for use in facilitating the placement of catheters within the coronary and peripheral vasculature. They are also for use in the placement of non-vascular catheters.	Class III
110538150	WORKER™ Standard J Curve	0.038" x 150 cm, 3 mm J, 3.5 cm soft tip		Class III
114035090	WORKER™ Amplatz Straight	0.035" x 90 cm, 7.5 cm soft tip		Class III
114035150	WORKER™ Amplatz Straight	0.035" x 150 cm, 7.5 cm soft tip		Class III
114035180	WORKER™ Amplatz Straight	0.035" x 180 cm, 7.5 cm soft tip		Class III
114035260	WORKER™ Amplatz Straight	0.035" x 260 cm, 7.5 cm soft tip		Class III
114135080	WORKER™ Amplatz Straight	0.035" x 80 cm, 3.5 cm soft tip		Class III

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Catalogue Number	Device Name	Specifications	Intended purpose per IFU	Classification
114135150	WORKER™ Amplatz Straight	0.035" x 150 cm, 3.5 cm soft tip	The intended use of Worker Guidewires is for use in facilitating the placement of catheters within the coronary and peripheral vasculature. They are also for use in the placement of non-vascular catheters.	Class III
114135180	WORKER™ Amplatz Straight	0.035" x 180 cm, 3.5 cm soft tip		Class III
114135260	WORKER™ Amplatz Straight	0.035" x 260 cm, 3.5 cm soft tip		Class III
114235090	WORKER™ Amplatz J Curve	0.035" x 90 cm, 3 mm J, 7.5 cm soft tip		Class III
114235150	WORKER™ Amplatz J Curve	0.035" x 150 cm, 3 mm J, 7.5 cm soft tip		Class III
116035180	WORKER™ Bentson type	0.035" x 180 cm, 15 cm soft tip		Class III

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Certificate History

Date	Reference Number	Action
31 March 2014	10144762	First Issue.
08 June 2018	8938885	Removal of reference to Becton Dickinson Infusion Therapy Systems Inc. from certificate address.
19 February 2019	7780687	Traceable to NB 0086.
Current	9665673	Certificate Renewal.

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Page 5 of 5

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