

EC Design-Examination Certificate

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

No.

CE 565720

Issued To:

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

In respect of:

Endomyocardial Biopsy Forceps

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: **2011-02-28**

Date: **2020-04-15**

Expiry Date: **2024-05-26**

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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

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Supplementary Information to CE 565720

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Product: Endomyocardial Forceps

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
190020	JAWZ Endomyocardial Biopsy Forcep	7.5F Straight 2.4mm x 50cm Non-fenestrated Jaw Formable – Stainless Steel	The 50cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right Ventricular Biopsies using the Jugular Approach, and for Right or Left Ventricular Pediatric Biopsies using the Femoral Approach	Class III
190030	JAWZ Endomyocardial Biopsy Forcep	7.5F Pre-Curve 2.4mm x 50cm Non-Fenestrated Jaw- Formable FEP Coated	The 50cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right Ventricular Biopsies using the Jugular Approach, and for Right or Left Ventricular Pediatric Biopsies using the Femoral Approach	Class III
190031	JAWZ Endomyocardial Biopsy Forcep	7.5F Maxi-Curve 2.4mm x 50cm Non-Fenestrated Jaw – Formable FEP Coated	The 50cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right Ventricular Biopsies using the Jugular Approach, and for Right or Left Ventricular Pediatric Biopsies using the Femoral Approach	Class III
190040	JAWZ Endomyocardial Biopsy Forcep	7.5F Straight 2.4mm x 105cm Non-Fenestrated Jaw – Formable Stainless Steel	The 105cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right or Left Ventricular Biopsies using the Femoral Approach.	Class III

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
190051	JAWZ Endomyocardial Biopsy Forcep	6F Maxi-Curve 1.8mm x 50cm Non-Fenestrated Jaw Formable FEP coated	The 50cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right Ventricular Biopsies using the Jugular Approach, and for Right or Left Ventricular Pediatric Biopsies using the Femoral Approach	Class III
190060	JAWZ Endomyocardial Biopsy Forcep	6F Straight 1.8mm x 50cm Non-Fenestrated Jaw Formable Stainless Steel	The 50cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right Ventricular Biopsies using the Jugular Approach, and for Right or Left Ventricular Pediatric Biopsies using the Femoral Approach	Class III
190065	JAWZ Endomyocardial Biopsy Forcep	6F Straight 1.8mm x 50cm Non-Fenestrated Jaw Non-Formable Stainless Steel	The 50cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right Ventricular Biopsies using the Jugular Approach, and for Right or Left Ventricular Pediatric Biopsies using the Femoral Approach	Class III
190066	JAWZ Endomyocardial Biopsy Forcep	6F Straight 1.8mm x 70cm Non-Fenestrated Jaw Formable FEP coated	The 70cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right Ventricular Biopsies using the Jugular Approach, and for Right or Left Ventricular Pediatric Biopsies using the Femoral Approach	Class III

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190070	JAWZ Endomyocardial Biopsy Forcep	6F Straight 1.8mm x 105cm Non-Fenestrated Jaw Formable Stainless Steel	The 105cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right or Left Ventricular Biopsies using the Femoral Approach	Class III
190075	JAWZ Endomyocardial Biopsy Forcep	6F Straight 1.8mm x 105cm Non-Fenestrated Jaw Non-Formable Stainless Steel	The 105cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right or Left Ventricular Biopsies using the Femoral Approach.	Class III
190080	JAWZ Endomyocardial Biopsy Forcep	7F Pre-curve 2.2mm x 50cm Non-Fenestrated Jaw Formable FEP coated	The 50cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right Ventricular Biopsies using the Jugular Approach, and for Right or Left Ventricular Pediatric Biopsies using the Femoral Approach	Class III
190081	JAWZ Endomyocardial Biopsy Forcep	7F Maxi-Curve 2.2mm x 50cm Non-Fenestrated Jaw Formable FEP coated	The 50cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right Ventricular Biopsies using the Jugular Approach, and for Right or Left Ventricular Pediatric Biopsies using the Femoral Approach	Class III

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190085	JAWZ Endomyocardial Biopsy Forcep	7F Straight 2.2mm x 105cm Non-Fenestrated Jaw Formable Stainless Steel	The 105cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right or Left Ventricular Biopsies using the Femoral Approach.	Class III
190086	JAWZ Endomyocardial Biopsy Forcep	7F Straight 2.2mm x 105cm Non-Fenestrated Jaw Formable FEP Coated	The 105cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right or Left Ventricular Biopsies using the Femoral Approach.	Class III
190090	JAWZ Endomyocardial Biopsy Forcep	5F Straight 1.5mm x 50cm Fenestrated Jaw Formable Stainless Steel	The 50cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right Ventricular Biopsies using the Jugular Approach, and for Right or Left Ventricular Pediatric Biopsies using the Femoral Approach	Class III
190095	JAWZ Endomyocardial Biopsy Forcep	5F Straight 1.5mm x 105cm Fenestrated Jaw Formable Stainless Steel	The 105cm Disposable Radiopaque Endomyocardial Biopsy Forceps are designed for Right or Left Ventricular Biopsies using the Femoral Approach.	Class III

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Certificate History

Date	Reference Number	Action
28 February 2011	10118187	First Issue - Transfer from another Notified Body.
03 December 2012	10137337	Certificate renewal.
23 November 2015	10159122	Addition of the Sterigenics location in Grand Prairie, TX as a sterilization location.
24 January 2018	8847348	Certificate renewal. Removal of product code 190061.
19 February 2019	7780687	Traceable to NB 0086.
Current	9784995	Certificate renewal and addition of device table.

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