

EC Design-Examination Certificate

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

No.**CE 608298**

Issued To:

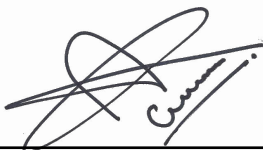
**Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens
Texas
75751
USA**

In respect of:

Atrieve™ Vascular Snare Kit

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):



Albert Roossien, Regulatory Lead

First Issued: **2014-02-28**Date: **2019-02-19**Expiry Date: **2019-02-27**

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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

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 608298

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Product: Atrieve™ Vascular Snare Kit

Product Code	Diameters (mm)	Working Diameter (mm)	Snare Length (cm)	Shaft Diameter (in)	Delivery Catheter Size (Fr)	Delivery Catheter Length (cm)	Delivery Catheter Inside Diameter (in)
381003004	4	2-4	175	0.018	3.2	150	0.030
381003008	8	4-8	175	0.018	3.2	150	0.030
382006010	10	6-10	120	0.026	6	100	0.062
382006015	15	9-15	120	0.026	6	100	0.062
382006020	20	12-20	120	0.026	6	100	0.062
382007030	30	18-30	120	0.026	7	100	0.074
382007045	45	27-45	120	0.026	7	100	0.074

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Certificate History

Date	Reference Number	Action
28 February 2014	10144761	First Issue.
08 June 2018	8938885	Removal of reference to Becton Dickinson Infusion Therapy Systems Inc. from certificate address.
Current	7780687	Traceable to NB 0086

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