



Declaration of Conformity

for

Atrieve™ Vascular Snare Kit

Catalog No.	Product Name
382006010	Atrieve Vascular Snare™ Kit, 6-10 mm diameter x 120 cm snare, 6F x 100 cm catheter
382006015	Atrieve Vascular Snare™ Kit, 9-15 mm diameter x 120 cm snare, 6F x 100 cm catheter
382006020	Atrieve Vascular Snare™ Kit, 12-20 mm diameter x 120 cm snare, 6F x 100 cm catheter
382007030	Atrieve Vascular Snare™ Kit, 18-30 mm diameter x 120 cm snare, 7F x 100 cm catheter
382007045	Atrieve Vascular Snare™ Kit, 27-45 mm diameter x 120 cm snare, 7F x 100 cm catheter
381003004	Atrieve Vascular Snare™ Kit, 2-4 mm diameter x 175 cm snare, 3.2F x 150 cm catheter
381003008	Atrieve Vascular Snare™ Kit, 4-8 mm diameter x 175 cm snare, 3.2F x 150 cm catheter

Product Classification: **Class III**
Annex IX, Rule 6 of MDD 93/42/EEC

Conformity Assessment Route: **Full Quality Assurance**
Annex II, excluding Section 4, of MDD 93/42/EEC
Design Examination
Annex II Section 4 of MDD 93/42/EEC

EC Certificate(s): CE Marking of Conformity Certificate No.: CE 565719
Design Examination Certificate No.: CE 608298

Manufacturer:	Authorized Representative:	Notified Body:
Argon Medical Devices, Inc.	Emergo Europe	BSI Group The Netherlands B.V.
1445 Flat Creek Road	Westervoortsedijk 60	Say Building
Athens, Texas 75751	6827 AT Arnhem	John M. Keynesplein 9
USA	The Netherlands	1066 EP Amsterdam
		Identification No.: 2797

We herewith declare under our sole responsibility that the products under this declaration are in conformity with the European Medical Devices Directive 93/42/EEC of 14 June 1993 (as amended by Directive 2007/47/EC). This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the Medical Devices Directive. The conformity to the Full Quality Assurance System and the design examination of the product under this declaration are described in the aforementioned EC Certificates issued and delivered by BSI.

Approved By:


Scott Bishop
Director, Regulatory Affairs

21-Jun-2023
Date