



Declaration of Conformity

for

SuperCore™ Biopsy Instrument

Product: Provided on following page(s)

Product Classification: Class IIa
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

EC Certificate CE Marking of Conformity Certificate No.: CE 565719

Manufacturer:	Authorized Representative:	Notified Body:
Argon Medical Devices, Inc. 1445 Flat Creek Road Athens, Texas 75751 USA	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 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, excluding Section 4, of the Medical Devices Directive. The conformity to the Full Quality Assurance System is described in the aforementioned EC certificate issued and delivered by BSI.

Approved By: Amy Clendening Wheeler
Amy Clendening-Wheeler
Regulatory Affairs Manager

March 26, 2021
Date

THIS DECLARATION OF CONFORMITY APPLIES TO THE FOLLOWING PRODUCTS:

Product Code	Product Name
701114060	SuperCore™ Biopsy Instrument 14ga x 6cm
701114090	SuperCore™ Biopsy Instrument 14ga x 9cm
701114150	SuperCore™ Biopsy Instrument 14ga x 15cm
701114200	SuperCore™ Biopsy Instrument 14ga x 20cm
701116060	SuperCore™ Biopsy Instrument 16ga x 6cm
701116090	SuperCore™ Biopsy Instrument 16ga x 9cm
701116150	SuperCore™ Biopsy Instrument 16ga x 15cm
701116200	SuperCore™ Biopsy Instrument 16ga x 20cm
701118060	SuperCore™ Biopsy Instrument 18ga x 6cm
701118090	SuperCore™ Biopsy Instrument 18ga x 9cm
701118150	SuperCore™ Biopsy Instrument 18ga x 15cm
701118200	SuperCore™ Biopsy Instrument 18ga x 20cm
701120060	SuperCore™ Biopsy Instrument 20ga x 6cm
701120090	SuperCore™ Biopsy Instrument 20ga x 9cm
701120150	SuperCore™ Biopsy Instrument 20ga x 15cm
701120200	SuperCore™ Biopsy Instrument 20ga x 20cm
701114060M	SuperCore™ Biopsy Instrument 14ga x 6cm - Mammotome
701114090M	SuperCore™ Biopsy Instrument 14ga x 9cm - Mammotome
701114150M	SuperCore™ Biopsy Instrument 14ga x 15cm - Mammotome
701116060M	SuperCore™ Biopsy Instrument 16ga x 6cm - Mammotome
701116090M	SuperCore™ Biopsy Instrument 16ga x 9cm - Mammotome
701116150M	SuperCore™ Biopsy Instrument 16ga x 15cm - Mammotome
Co-Packaged SuperCore™ Biopsy Kit	
701214090	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701214150	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701214200	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701216090	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701216150	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701216200	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701218090	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701218150	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701218200	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701220090	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701220150	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
701220200	SuperCore™ Biopsy Instrument with Co-Axial Introducer Needle
SABD-1409-15-T	Single Action Biopsy Device 14g (2.1mm) x 9cm
SABD-1415-15-T	Single Action Biopsy Device 14g (2.1mm) x 15cm
SABD-1609-15-T	Single Action Biopsy Device 16g (1.7mm) x 9cm
SABD-1615-15-T	Single Action Biopsy Device 16g (1.7mm) x 15cm
SABD-1620-15-T	Single Action Biopsy Device 16g (1.7mm) x 20cm
SABD-1809-15	Single Action Biopsy Device 18ga (1.3mm) x 9cm
SABD-1809-15-T	Single Action Biopsy Device 18g (1.3mm) x 9cm
SABD-1815-15	Single Action Biopsy Device 18g (1.3mm) x 15cm
SABD-1815-15-T	Single Action Biopsy Device 18g (1.3mm) x 15cm
SABD-1820-15-T	Single Action Biopsy Device 18g (1.3mm) x 20cm
SABD-2009-15-T	Single Action Biopsy Device 20g (0.9mm) x 9cm
SABD-2015-15-T	Single Action Biopsy Device 20g (0.9mm) x 15cm
SABD-2015-15	Single Action Biopsy Device 20ga (0.9mm) x 15cm
SABD-2020-15	SABD 20g x 20cm 20mmT
SABD-2020-15-T	Single Action Biopsy Device 20ga (0.9mm) x 20cm
620916	Accucore Single Action Core Biopsy Device 16ga x 3 1/2"(9cm)

Product Code	Product Name
620918	Accucore Single Action Core Biopsy Device 18ga x 3 1/2"(9cm)
620920	Accucore Single Action Core Biopsy Device 20ga x 3 1/2"(9cm)
621516	Accucore Single Action Core Biopsy Device 16ga x 6" (15cm)
621518	Accucore Single Action Core Biopsy Device 18ga x 6"(15cm)
621520	Accucore Single Action Core Biopsy Device 20ga x 6"(15cm)
640914	Accucore Single Action Core Biopsy Device 14ga x 3 1/2"(9cm)
641514	Accucore Single Action Core Biopsy Device 14ga x 6"(15cm)
Co-Packaged SABD	
CS-1409-15-T	Coaxial SABD Biopsy Device 14G (2.1mm) x 9cm
CS-1415-15-T	Coaxial SABD Biopsy Device 14G (2.1mm) x 15cm
CS-1609-15-T	Coaxial SABD Biopsy Device 16G (1.7mm) x 9cm
CS-1615-15-T	Coaxial SABD Biopsy Device 16G (1.7mm) x 15cm
CS-1620-15-T	Coaxial SABD Biopsy Device 16G (1.7mm) x 20cm
CS-1809-15-T	Coaxial SABD Biopsy Device 18G (1.3mm) x 9cm
CS-1815-15-T	Coaxial SABD Biopsy Device 18G (1.3mm) x 15cm
CS-1815-15	Coaxial SABD Biopsy Device 18G (1.3mm) x 15cm
CS-1820-15-T	Coaxial SABD Biopsy Device 18G (1.3mm) x 20cm
CS-2009-15-T	Coaxial SABD Biopsy Device 20G (0.9mm) x 9cm
CS-2015-15-T	Coaxial SABD Biopsy Device 20G (0.9mm) x 15cm
CS-2015-15	Coaxial SABD Biopsy Device 20G (0.9mm) x 15cm
CS-2020-15-T	Coaxial SABD Biopsy Device 20G (0.9mm) x 20cm

End of Product List