



# 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

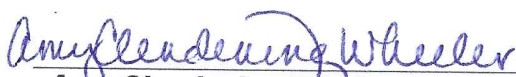
**EC Certificate** CE Marking of Conformity Certificate No.: CE 565719

|                                                                                   |                                                                             |                                                                                                                          |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| <b>Manufacturer:</b>                                                              | <b>Authorized Representative:</b>                                           | <b>Notified Body:</b>                                                                                                    |
| Argon Medical Devices, Inc.<br>1445 Flat Creek Road<br>Athens, Texas 75751<br>USA | Emergo Europe<br>Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands | BSI Group The Netherlands B.V.<br>Say Building<br>John M. Keynesplein 9<br>1066 EP Amsterdam<br>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**  
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         |
| <b>Co-Packaged SuperCore™ Biopsy Kit</b> |                                                              |
| 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)    |
| <b>Co-Packaged SABD</b> |                                                              |
| 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\***