



Declaration of Conformity

for

Pro-Mag™ Biopsy Needles

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:

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

Authorized Representative:

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Notified Body:

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:


Scott Bishop

Director of Regulatory Affairs


Date

THIS DECLARATION OF CONFORMITY APPLIES TO THE FOLLOWING PRODUCTS:

Product Code	Product Name
765114080	Pro-Mag™ Biopsy Needles
765114120	Pro-Mag™ Biopsy Needles
765114160	Pro-Mag™ Biopsy Needles
765116080	Pro-Mag™ Biopsy Needles
765116120	Pro-Mag™ Biopsy Needles
765116160	Pro-Mag™ Biopsy Needles
765118080	Pro-Mag™ Biopsy Needles
765118120	Pro-Mag™ Biopsy Needles
765118160	Pro-Mag™ Biopsy Needles
765120080	Pro-Mag™ Biopsy Needles
765120120	Pro-Mag™ Biopsy Needles
765120160	Pro-Mag™ Biopsy Needles
765014100	Pro-Mag™ Biopsy Needles
765014120	Pro-Mag™ Biopsy Needles
765014160	Pro-Mag™ Biopsy Needles
765014200	Pro-Mag™ Biopsy Needles
765016100	Pro-Mag™ Biopsy Needles
765016160	Pro-Mag™ Biopsy Needles
765016200	Pro-Mag™ Biopsy Needles
765016250	Pro-Mag™ Biopsy Needles
765016600	Pro-Mag™ Biopsy Needles
765018100	Pro-Mag™ Biopsy Needles
765018160	Pro-Mag™ Biopsy Needles
765018200	Pro-Mag™ Biopsy Needles
765018250	Pro-Mag™ Biopsy Needles
765018300	Pro-Mag™ Biopsy Needles
765020100	Pro-Mag™ Biopsy Needles
765020160	Pro-Mag™ Biopsy Needles
765020200	Pro-Mag™ Biopsy Needles

End of Product List