ARGON
MEDICAL DEVICES

Declaration of Conformity

for

Pro-Mag® Ultra Automatic Biopsy Instrument

Product Code	Product Description
7675	Pro-Mag® Ultra Automatic Biopsy Instrument
7676	Pro-Mag® Ultra ST Automatic Biopsy Instrument
7677	Pro-Mag® Ultra 2.2 Automatic Biopsy Instrument

Product Classification: Class I
Annex IX, Rule 1 of MDD 93/42/EEC

Conformity Assessment Route: Quality Management System
Annex VII of MDD 93/42/EEC

EC Declaration of Conformity: ISO 13485:2016 Quality Management System
Certificate Number: FM 700791

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

Authorized Representative:
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

We herewith declare under our sole responsibility that the products listed in this Declaration are in conformity with Annex VII of the European Medical Devices Directive 93/42/EEC of 14 June 1993, as amended by Directive 2007/47/EC. The products are designed, manufactured and distributed in compliance with the Quality Management System described in the aforementioned certificate issued and delivered by BSI.

Approved By:

Scott Bishop
Director of Regulatory Affairs

Digitally signed by Ostapciuc Alexandr
Date: 2023.08.08 12:47:52 EEST
Reason: MoldSign Signature
Location: Moldova

07/20/2023
Date