



# Declaration of Conformity

for

## Skin Fixation Disks

Product Code	Product Name	Product Classification
802500000	Skin Fix™	Class Is Annex IX, Rule 1 of MDD 93/42/EEC
802500001	Skater™ Fix	Class Is Annex IX, Rule 4 of MDD 93/42/EEC

**Conformity Assessment Route:** Production Quality Assurance  
Annex V, of MDD 93/42/EEC

**EC Certificate:** CE Marking of Conformity Certificate No.: CE 566724

**Manufacturer:**

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

**Authorized Representative:**

**Emergo Europe**  
Prinsessegracht 20  
2514 AP The Hague  
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 and conformity to Annex V of the Medical Devices Directive relevant to sterility in the manufacture of the products concerned. The conformity to the relevant aspects of Annex V is described in the aforementioned Production Quality Assurance certificate issued and delivered by BSI.

Approved By:

Rebecca L. Ellis  
Vice President of RA and QA

27 Feb 2019

Date