By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 565720**

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

In respect of:

Endomyocardial Biopsy Forceps

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2011-02-28** Date: **2019-02-19** Expiry Date: **2022-12-01**

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EC Design-Examination Certificate

Supplementary Information to CE 565720

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Product: Endomyocardial Forceps

Code	Product description
190020	Forceps, BIO/50/2.4/7.5F/STR/SS 05/1999
190030	Forceps, BIO/50/2.4/7.5F/PRE/FEB 05/1999
190031	Forceps, BIO/50/2.4/7.5F/MCURVE 05/1999
190040	Forceps, BIO/2.4/STR/SS/7.5F 05/1999
190051	Forceps, BIOPSY/50/1.8/MCURVE/FEP/5.5F 05/1999
190060	Forceps, BIOPSY/50/1.8/STR/SS/5.5F 05/1999
190065	Forceps, BIO/50/1.8/STR/SS/5.5F 05/1999
190066	Forceps, BIO/70/1.8/STR/FEP/5.5F 05/1999
190070	Forceps, BIOPSY/105/1.8/STR/SS/5.5F 05/1999
190075	Forceps, BIO/105/1.8/STR/SS/5.5F 05/1999
190080	Forceps, BIO/50/2.2/PRE/FEP/7F 05/1999
190081	Forceps, BIO/50/2.2/MCURVE/FEP/7F 05/1999
190085	Forceps, BIO/105/2.2/7F/STR/SS 05/1999
190086	Forceps, BIO/105/2.2/7F/STR/FEB 05/1999
190090	Forceps, BIO/50/1.5/5F/STR/SS 05/1999
190095	Forceps, BIO/105/1.5/5F/STR/SS 05/1999

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Certificate History

Date	Reference Number	Action
28 February 2011	10118187	First Issue - Transfer from another Notified Body.
03 December 2012	10137337	Certificate renewal.
23 November 2015	10159122	Addition of the Sterigenics location in Grand Prairie, TX as a sterilization location.
24 January 2018	8847348	Certificate renewal. Removal of product code 190061.
Current	7780687	Traceable to NB 0086.

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