EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 744183 R000

Manufacturer: Argon Medical Devices, Inc.

Address:
1445 Flat Creek Road
Athens
Texas
75751
USA

Single Registration Number: US-MF-000002324

EU Authorised Representative: Emergo Europe B.V.

Address:
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-05-24**

Current Issue Date: **2025-12-02**

Starting Validity Date: **2025-12-02**

Expiry Date: **2029-05-23**

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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
WORKER™ Guidewire (Standard, Amplatz and Bentson)	See MDR 762338
Amplatz Guidewire	See MDR 762338
Guidewires	See MDR 744230
Class IIb, Implantable	**Intended purpose**
SKATER™ All Purpose and Nephrostomy Drainage Catheters SKATER™ Mini-Loop Drainage Sets SKATER™ Single Step Drainage Set SKATER™ Drainage Catheter SKATER™ Nephrostomy Catheter SKATER™ Biliary Drainage Catheter SKATER™ Nephrostomy Kit SKATER™ Introducer Nephrostomy Kit SKATER™ Introducer Biliary Drainage Kit	See MDR 762331
Class IIb	**Intended purpose**
Angiography and Haemodynamic Devices	Disruption and removal of thrombus.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Access Devices	Class IIa
Introducer Sets	Class IIa
Devices for Administration, Withdrawal and Collection	Class IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-05-24	3386437	Issued
Current	30399321	Supplemented – Addition of Class IIb Implantable SKATER™ Drainage Catheter and Kit models; addition of Angiography and Haemodynamic Devices Class IIb group; addition of Introducer Sets and Devices for Administration, Withdrawal and Collection Class IIa categories.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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A Member of the BSI Group of Companies.