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

6 February 2024

Notified Body Confirmation Letter
Reference: EU2023-607/651169

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens, TX
75751
USA
SRN Number (if available): US-MF-000002324

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the

corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Atrieve Vascular Snare Kit	*Class III*	*Not Applicable*	**CE 608298, 2797 CE 565719, 2797**
Option Elite Vena Cava Filter System	*Class III*	*Not Applicable*	**CE 649387, 2797 CE 565719, 2797**
Jawz Endomyocardial Biopsy Forceps	*Class III*	*Not Applicable*	**CE 565720, 2797 CE 565719, 2797**
Worker Guidewires	*Class III*	*Not Applicable*	**CE 608299, 2797 CE 565719, 2797**
Cleaner Rotational Thrombectomy Device	*Class IIb - Non Implantable*	*Not Applicable*	**CE 565719, 2797**
Skater Drainage Catheters and Kits	*Class IIb - Implantable - Non WET*	*Not Applicable*	**CE 565719, 2797**
Guidewires [Worker, Lunderquist, Stainless Steel, Pointer, Access] (Access Devices)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Access Needles / Puncture Needle [Hawkins blunt, Trocar, and Stainless Steel/ (Devices for administration, channelling and removal of fluid)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Guidewire Introducer Needles/Vascular Access Needle Device [Guidewire Introducer Needle, "Window Wall" Guidewire needle, Seldinger Needles AMC Arterial Needle, Percutaneous Entry	*Class IIa*	*Not Applicable*	**CE 565719, 2797**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Needle, Cournand-Style Needle, Modified Cournand-Style Needle, AMC Winged Arterial Needle] (Access Device)			
PTC Catheter and Introducer Sheath Needles, Dilator (Devices for administration, channelling and removal of fluid)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
V-Stick Vascular Access Set (Access Devices)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Introducer Kits (Access Devices)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Skater Introducer and Sets (Access Devices)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Fluid Management Devices [Manifolds, Stopcocks, Monitoring lines, Waste bags, High Pressure Lines, Connectors] (Devices for administration, channelling and removal of fluid)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Biopince and Biopince Ultra Automatic Full Core Biopsy Instrument (Active Biopsy)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Breast Localization Needles (BLN) [Homer, Hawkins, D.wire, Accura]	*Class IIa*	*Not Applicable*	**CE 565719, 2797**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
(Biopsy Localization and access Devices)			
Bone Needles [Bone Marrow Harvest Needle, Bone Marrow Aspiration, T-Lok Bone Marrow Biopsy Needle, Pediatric Bone Marrow Needle, Osty-Core Bone Biopsy Needles and Bone Access] (Biopsy Localization and access Devices)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Co-Axial Introducer Needle (Biopsy Localization and access Devices)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Manual Biopsy Needles (FNA) (Biopsy Localization and access Devices)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Supercore Semi-Automatic Biopsy Instrument (Active Biopsy)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Tru-Core II Automatic Biopsy Instrument (Active Biopsy)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
TLAB Transjugular Liver Biopsy System (Active Biopsy)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
ProMag Ultra Needles and ACN Needles (Active Biopsy)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Prostate Stabilization and Seeding Set (Biopsy Localization and access Devices)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**
Ultracore Biopsy Needle (Active Biopsy)	*Class IIa*	*Not Applicable*	**CE 565719, 2797**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
HSG Catheters	*Class Is*	*Not Applicable*	**CE 566724, 2797**
Galactography	*Class Is*	*Not Applicable*	**CE 566724, 2797**
Needle Guide	*Class Is*	*Not Applicable*	**CE 566724, 2797**
Drainage Bag	*Class Is*	*Not Applicable*	**CE 566724, 2797**
Connecting Tubes (for drainage and connectors)	*Class Is*	*Not Applicable*	**CE 566724, 2797**
Skin Fixation Device (Skater Fix only)	*Class Is*	*Not Applicable*	**CE 566724, 2797**
Argon Guidewires [Stainless Steel and PTFE Coated Stainless Steel Guidewires]	*Class III*	*Not Applicable*	**CE 565721, 2797** **CE 565719, 2797**
Pro-Mag Ultra Reusable Biopsy Instrument	*Class Ir*	*Not Applicable*	**Not Applicable** **2797**

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not applicable	Not applicable	Not applicable	Not applicable

Confirmation Letter Revision History

Date	Action
2024/02/06	Initial issue