

Manufacturer's Declaration

In relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Argon Medical Devices, Inc.
Manufacturer address and contact details	1445 Flat Creek Road Athens, TX 75751 USA
Single Registration Number (SRN) (if available)	US-MF-000002324

Authorised Representative name (if applicable)	Emergo Europe B.V. - [Netherlands]
Authorised Representative address and contact details	Westervoortsedijk 60 Arnhem 6827 AT, Netherlands
Single Registration Number (SRN) (if available)	NL-AR-000000116

Notified body name (if applicable)	BSI	<input checked="" type="checkbox"/> See attached schedule
Notified body number (if applicable)	2797	<input checked="" type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)		<input checked="" type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)		<input checked="" type="checkbox"/> See attached schedule
End date of extended validity/transition period		<input checked="" type="checkbox"/> See attached schedule

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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We, as the manufacturer declare under our sole responsibility:

- for the listed **Directive Certificates** in the attached schedule the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

☐ Expired *before* 20 March 2023:

Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s).

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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- ☐ Expired/expires after 20 March 2023:

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➤ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➤ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of Argon Medical Devices, Inc.:

Argon Medical Devices, Inc.
Plano, Texas USA
15-February 2024



Scott Bishop, Vice President, Regulatory Affairs
Scott.bishop@argonmedical.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) ³ (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Atrieve Vascular Snare Kit	CE 608298 CE 565719	02/27/2024 05/26/2024	BSI 2797	BSI 2797	31-Dec-2027	Not Applicable
Option Elite Vena Cava Filter System	CE 649387 CE 565719	02/16/2024 05/26/2024	BSI 2797	BSI 2797	31-Dec-2027	Not Applicable
Jawz Endomyocardial Biopsy Forceps	CE 565720 CE 565719	05/26/2024 05/26/2024	BSI 2797	BSI 2797	31-Dec-2027	Not Applicable
Worker Guidewires	CE 608299 CE 565719	03/30/2024 05/26/2024	BSI 2797	BSI 2797	31-Dec-2027	Not Applicable
Argon Guidewires [Stainless Steel and PTFE Coated Stainless Steel Guidewires]	CE 565721 CE 565719	12/01/2022 05/26/2024	BSI 2797	BSI 2797	31-Dec-2027	Not Applicable
Cleaner Rotational Thrombectomy Device	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Skater Drainage Catheters and Kits	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2027	Not Applicable
Guidewires [Worker, Lunderquist, Stainless Steel, Pointer, Access] (Access Devices)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable

³ for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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Access Needles / Puncture Needle [Hawkins blunt, Trocar, and Stainless Steel/ (Devices for administration, channeling and removal of fluid)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Guidewire Introducer Needles/Vascular Access Needle Device [Guidewire Introducer Needle, "Window Wall" Guidewire needle, Seldinger Needles AMC Arterial Needle, Percutaneous Entry Needle, Cournand-Style Needle, Modified Cournand-Style Needle, AMC Winged Arterial Needle] (Access Device)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable

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PTC Catheter and Introducer Sheath Needles, Dilator (Devices for administration, channeling and removal of fluid)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
V-Stick Vascular Access Set (Access Devices)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Introducer Kits (Access Devices)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Skater Introducer and Sets (Access Devices)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Fluid Management Devices [Manifolds, Stopcocks, Monitoring lines, Waste bags, High Pressure Lines, Connectors] (Devices for administration, channeling and removal of fluid)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Biopince and Biopince Ultra Automatic Full Core Biopsy Instrument (Active Biopsy)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable

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Breast Localization Needles (BLN) [Homer, Hawkins, D.wire, Accura] (Biopsy Localization and access Devices)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
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)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Co-Axial Introducer Needle (Biopsy Localization and access Devices)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Manual Biopsy Needles (FNA) (Biopsy Localization and access Devices)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable

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Supercore Semi-Automatic Biopsy Instrument (Active Biopsy)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Tru-Core II Automatic Biopsy Instrument (Active Biopsy)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
TLAB Transjugular Liver Biopsy System (Active Biopsy)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
ProMag Ultra Needles and ACN Needles (Active Biopsy)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Prostate Stabilization and Seeding Set (Biopsy Localization and access Devices)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Ultracore Biopsy Needle (Active Biopsy)	CE 565719	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
HSG Catheters	CE 566724	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Galactography	CE 566724	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Needle Guide	CE 566724	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Drainage Bag	CE 566724	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable

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Connecting Tubes (for drainage and connectors)	CE 566724	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Skin Fixation Device (Skater Fix only)	CE 566724	05/26/2024	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable
Pro-Mag Ultra Reusable Biopsy Instrument	Not Applicable	Not Applicable	BSI 2797	BSI 2797	31-Dec-2028	Not Applicable

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