

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

## MDR 744230 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.

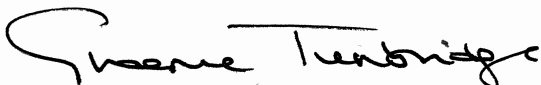
**Address:**

Westervoortsedijk 60  
6827 AT Arnhem  
The Netherlands

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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: **2024-05-24**

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### Device Schedule:

**Device Name:** Guidewires

**Intended Purpose per IFU:** Guidewires are intended to facilitate the percutaneous placement of intravascular and non-vascular devices during diagnostic and intervention procedures.

**Type** (Codes as per (EU) 2017/2185): MDN 1203

**Risk Classification:** Class III

| Description   | Model  | Basic UDI-DI    |
|---|--------|-----------------|
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J                 | 388273 | 08863332700062N |
| Diameter .038" x Length 150cm Type: Fixed Core Config: 3J                 | 388275 |                 |
| Diameter .025" x Length 125cm Type: Fixed Core Config: 3J                 | 395270 |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J                 | 395273 |                 |
| Diameter .038" x Length 150cm Type: Fixed Core Config: 3J                 | 395275 |                 |
| Diameter .032" x Length 150cm Type: Fixed Core Config: 3J                 | 395603 |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 388282 |                 |
| Diameter .038" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 388284 |                 |
| Diameter .035" x Length 175cm Type: Fixed Core Config: 3J Coating: PTFE   | 388768 |                 |
| Diameter .035" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE   | 388794 |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 395183 | 08863332700042J |
| Diameter .025" x Length 125cm Type: Fixed Core Config: 3J Coating: PTFE   | 395279 |                 |
| Diameter .035" x Length 125cm Type: Fixed Core Config: 3J Coating: PTFE   | 395281 |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 395282 |                 |
| Diameter .038" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 395284 |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 6J Coating: PTFE   | 395289 |                 |
| Diameter .021" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE   | 395406 |                 |
| Diameter .025" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE | 395420 |                 |
| Diameter .018" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 395465 |                 |
| Diameter .018" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE | 395470 |                 |

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| Description   | Model   | Basic UDI-DI    |
|---|---------|-----------------|
| Diameter .021" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 395523  | 08863332700042J |
| Diameter .025" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 395559  |                 |
| Diameter .025" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE   | 395585  |                 |
| Diameter .032" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 395600  |                 |
| Diameter .032" x Length 125cm Type: Fixed Core Config: 3J Coating: PTFE   | 395613  |                 |
| Diameter .032" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE   | 395622  |                 |
| Diameter .035" x Length 200cm Type: Fixed Core Config: 3J Coating: PTFE   | 395722  |                 |
| Diameter .035" x Length 175cm Type: Fixed Core Config: 3J Coating: PTFE   | 395768  |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 7.5J Coating: PTFE | 395780  |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE | 395787  |                 |
| Diameter .035" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE   | 395794  |                 |
| Diameter .038" x Length 200cm Type: Fixed Core Config: 3J Coating: PTFE   | 395817  |                 |
| Diameter .038" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE   | 395839  |                 |
| Diameter .038" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE | 395863  |                 |
| Diameter .032" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE | 395900  |                 |
| Diameter .028" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 395961  |                 |
| Diameter .030" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | 395991  |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | A395282 |                 |
| Diameter .038" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | A395284 |                 |
| Diameter .035" x Length 180cm Type: Fixed Core Config: 3J Coating: PTFE   | A395482 |                 |
| Diameter .025" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | A395559 |                 |
| Diameter .032" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE   | A395600 |                 |
| Diameter .032" x Length 125cm Type: Fixed Core Config: 3J Coating: PTFE   | A395613 |                 |
| Diameter .035" x Length 200cm Type: Fixed Core Config: 3J Coating: PTFE   | A395722 |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE | A395787 |                 |
| Diameter .032" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE | A395900 |                 |

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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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| Description   | Model   | Basic UDI-DI    |
|---|---------|-----------------|
| Diameter .035" x Length 180cm Type: Fixed Core Config: Bentson<br>Coating: PTFE | 395170  | 08863332700122H |
| Diameter .035" x Length 150cm Type: Fixed Core Config: BENTSON<br>Coating: PTFE | 395930E |                 |
| Diameter .032" x Length 150cm Type: Fixed Core Config: BENTSON<br>Coating: PTFE | 395931  |                 |
| Diameter .038" x Length 150cm Type: Fixed Core Config: BENTSON<br>Coating: PTFE | 395933C |                 |
| Diameter .035" x Length 150cm Type: Movable Core Config: 3J<br>Coating: PTFE    | 388300  | 08863332700142M |
| Diameter .032" x Length 150cm Type: Movable Core Config: 3J<br>Coating: PTFE    | 395309  |                 |
| Diameter .038" x Length 150cm Type: Movable Core Config: 3J<br>Coating: PTFE    | 395315  |                 |
| Diameter .035" x Length 150cm Type: Movable Core Config: 3J<br>Coating: PTFE    | 395320  |                 |
| Diameter .038" x Length 260cm Type: Movable Core Config: 3J<br>Coating: PTFE    | 395330  |                 |
| Diameter .035" x Length 125cm Type: Movable Core Config: 6J<br>Coating: PTFE    | 395337  |                 |
| Diameter .035" x Length 150cm Type: Movable Core Config: 1.5J<br>Coating: PTFE  | 395398  |                 |
| Diameter .035" x Length 200cm Type: Movable Core Config: 3J<br>Coating: PTFE    | 395656  |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/XTB<br>Coating: PTFE  | 390282  | 08863332700302K |

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| Description   | Model  | Basic UDI-DI    |
|---|--------|-----------------|
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/XTB/Z<br>Coating: PTFE      | 390182 | 08863332700202G |
| Diameter .035" x Length 175cm Type: Fixed Core Config: 3J/XTB/Z<br>Coating: PTFE      | 390186 |                 |
| Diameter .038" x Length 150cm Type: Fixed Core Config: 3J/XTB/Z<br>Coating: PTFE      | 390284 |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/HD/Z<br>Coating: PTFE       | 393182 | 08863332700182V |
| Diameter .038" x Length 150cm Type: Fixed Core Config: 3J/HD/Z<br>Coating: PTFE       | 393184 |                 |
| Diameter .035" x Length 175cm Type: Fixed Core Config: 3J/HD/Z<br>Coating: PTFE       | 393186 |                 |
| Diameter .038" x Length 175cm Type: Fixed Core Config: 3J/HD/Z<br>Coating: PTFE       | 393187 |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/Z<br>Coating: PTFE          | 393282 | 08863332700212J |
| Diameter .035" x Length 260cm Type: Fixed Core Config: ST/HD<br>Mullins Coating: PTFE | 395073 | 088633327002932 |
| Diameter .035" x Length 180cm Type: Fixed Core Config: DE-3J&ST<br>Coating: PTFE      | 393999 | 08863332700242Q |
| Diameter .035" x Length 150cm Type: Fixed Core Config: DE-3J&ST<br>Coating: PTFE      | 395112 |                 |
| Diameter .021" x Length 125cm Type: Fixed Core Config: ST                             | 395205 | 08863332700072Q |
| Diameter .025" x Length 125cm Type: Fixed Core Config: ST                             | 395208 |                 |
| Diameter .032" x Length 150cm Type: Fixed Core Config: ST                             | 395212 |                 |
| Diameter .021" x Length 150cm Type: Fixed Core Config: ST                             | 395509 |                 |

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| Description  | Model   | Basic UDI-DI    |
|--|---------|-----------------|
| Diameter .025" x Length 125cm Type: Fixed Core Config: ST Coating: PTFE    | 395224  | 08863332700052L |
| Diameter .025" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE    | 395225  |                 |
| Diameter .032" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE    | 395228  |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE    | 395231  |                 |
| Diameter .038" x 150cm Type: Fixed Core Config: ST Coating: PTFE           | 395234  |                 |
| Diameter .025" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE    | 395367  |                 |
| Diameter .032" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE    | 395368  |                 |
| Diameter .035" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE    | 395369  |                 |
| Diameter .038" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE    | 395370  |                 |
| Diameter .018" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE    | 395457  |                 |
| Diameter .018" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE    | 395469  |                 |
| Diameter .021" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE    | 395501  |                 |
| Diameter .021" x Length 125cm Type: Fixed Core Config: ST Coating: PTFE    | 395504  |                 |
| Diameter .021" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE    | 395522  |                 |
| Diameter .035" x Length 200cm Type: Fixed Core Config: ST Coating: PTFE    | 395703  |                 |
| Diameter .028" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE    | 395884  |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE    | A395231 |                 |
| Diameter .035" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE    | A395369 |                 |
| Diameter .035" x Length 150cm Type: Movable Core Config: ST Coating: PTFE  | 388301  |                 |
| Diameter .035" x Length 150cm Type: Movable Core Config: ST Coating: PTFE  | 395258  |                 |
| Diameter .038" x Length 150cm Type: Movable Core Config: ST Coating: PTFE  | 395261  |                 |
| Diameter .038" x Length 260cm Type: Movable Cable Config: ST Coating: PTFE | 395333  |                 |

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| Description   | Model   | Basic UDI-DI    |
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| Diameter .035" x Length 150cm Type: Fixed Core Config: 1.5J/HD Coating: PTFE    | 395280  | 08863332700132K |
| Diameter .032" x Length 150cm Type: Fixed Core Config: 3J/HD Coating: PTFE      | 395332  |                 |
| Diameter .035" x Length 180cm Type: Fixed Core Config: 1.5J/HD Coating: PTFE    | 395350  |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/HD Coating: PTFE      | 395993  |                 |
| Diameter .038" x Length 150cm Type: Movable Core Config: 3J/HD Coating: PTFE    | 395266  | 08863332700272W |
| Diameter .035" x Length 150cm Type: Movable Core Config: 3J/HD Coating: PTFE    | 395312  |                 |
| Diameter .035" x Length 150cm Type: Movable Core Config: 3J/HD Coating: PTFE    | A395312 |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: DE/LT&1.5J Coating: PTFE | 395919  | 08863332700222L |
| Diameter .035" x Length 150cm Type: Fixed Core Config: DE-3J&LT Coating: PTFE   | 395345  |                 |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 15J/LT Coating: PTFE     | 395352  | 08863332700172T |
| Diameter .035" x Length 150cm Type: Fixed Core Config: LT Coating: PTFE         | 395382  | 08863332700152P |
| Diameter .035" x Length 150cm Type: Fixed Core Config: LLT Coating: PTFE        | 395384  |                 |
| Diameter .035" x 145cm Type: Movable Core Config: LT/3J Coating: PTFE           | 395721  | 08863332700162R |
| Diameter .035" x Length 150cm Type: Fixed Core Config: ST/HD Coating: PTFE      | 395687  | 08863332700262U |
| Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/LLT Coating: PTFE     | 395708  | 08863332700192X |
| Diameter .015" x Length 150cm Type: Fixed Core Config: Mullins                  | 395979  | 08863332700012C |
| Diameter .017" x Length 150cm Type: Fixed Core Config: Mullins                  | 395980  |                 |

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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 |
|---------|------------------|--------|
| Current | 3386617          | Issued |



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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.  
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