

UKCA Design-Examination Certificate

Part II of The Medical Devices Regulations 2002, Annex II Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

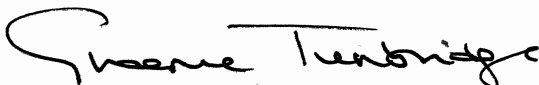
No. **UKCA 759765**
Issued To: **Argon Medical Devices, Inc.**
1445 Flat Creek Road
Athens
Texas
75751
USA

In respect of:

Guidewires

BSI has performed a design examination of the above devices in accordance with Part II of The Medical Devices Regulations 2002, Annex II Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The design conforms to the requirements of this regulation. For the placing on the market of these products an Annex II (modified as described above) excluding Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2024-06-17**

Date: **2024-06-17**

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

...making excellence a habit.™

UKCA Design-Examination Certificate

Supplementary Information to UKCA 759765

Issued To:

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

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.

Classification: Class III

Catalogue Number	Model, Type
388273	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J
388275	Diameter .038" x Length 150cm Type: Fixed Core Config: 3J
395270	Diameter .025" x Length 125cm Type: Fixed Core Config: 3J
395273	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J
395275	Diameter .038" x Length 150cm Type: Fixed Core Config: 3J
395603	Diameter .032" x Length 150cm Type: Fixed Core Config: 3J
388282	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
388284	Diameter .038" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
388768	Diameter .035" x Length 175cm Type: Fixed Core Config: 3J Coating: PTFE
388794	Diameter .035" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE
395183	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE

First Issued: **2024-06-17**

Date: **2024-06-17**

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

...making excellence a habit.™

UKCA Design-Examination Certificate

Supplementary Information to UKCA 759765

Issued To:

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

Catalogue Number	Model, Type
395279	Diameter .025" x Length 125cm, Type: Fixed Core, Config:3J, Coating: PTFE
395281	Diameter .035" x Length 125cm Type: Fixed Core Config: 3J Coating: PTFE
395282	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
395284	Diameter .038" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
395289	Diameter .035" x Length 150cm Type: Fixed Core Config: 6J Coating: PTFE
395406	Diameter .021" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE
395420	Diameter .025" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE
395465	Diameter .018" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
395470	Diameter .018" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE
395523	Diameter .021" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
395559	Diameter .025" x Length 150cm, Type: Fixed Core, Config:3J, Coating: PTFE
395585	Diameter .025" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE
395600	Diameter .032" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
395613	Diameter .032" x Length 125cm Type: Fixed Core Config: 3J Coating: PTFE
395622	Diameter .032" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE

First Issued: **2024-06-17**

Date: **2024-06-17**

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

...making excellence a habit.™

UKCA Design-Examination Certificate

Supplementary Information to UKCA 759765

Issued To:

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

Catalogue Number	Model, Type
395722	Diameter .035" x Length 200cm Type: Fixed Core Config: 3J Coating: PTFE
395768	Diameter .035" x Length 175cm Type: Fixed Core Config: 3J Coating: PTFE
395780	Diameter .035" x Length 150cm Type: Fixed Core Config: 7.5J Coating: PTFE
395787	Diameter .035" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE
395794	Diameter .035" x Length 260cm Type: Fixed Core Config: 3J Coating: PTFE
395817	Diameter .038" x Length 200cm Type: Fixed Core Config: 3J Coating: PTFE
395839	Diameter .038" x Length 260cm, Type: Fixed Core, Config: 3J, Coating: PTFE
395863	Diameter .038" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE
395900	Diameter .032" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE
395961	Diameter .028" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
395991	Diameter .030" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
A395282	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
A395284	Diameter .038" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
A395482	Diameter .035" x Length 180cm Type: Fixed Core Config: 3J Coating: PTFE
A395559	Diameter .025" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE

First Issued: **2024-06-17**

Date: **2024-06-17**

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

...making excellence a habit.™

UKCA Design-Examination Certificate

Supplementary Information to UKCA 759765

Issued To:

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

Catalogue Number	Model, Type
A395600	Diameter .032" x Length 150cm Type: Fixed Core Config: 3J Coating: PTFE
A395613	Diameter .032" x Length 125cm Type: Fixed Core Config: 3J Coating: PTFE
A395722	Diameter .035" x Length 200cm Type: Fixed Core Config: 3J Coating: PTFE
A395787	Diameter .035" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE
A395900	Diameter .032" x Length 150cm Type: Fixed Core Config: 1.5J Coating: PTFE
395170	Diameter .035" x Length 180cm Type: Fixed Core Config: BENTSON Coating: PTFE
395930E	Diameter .035" x Length 150cm Type: Fixed Core Config: BENTSON Coating: PTFE
395931	Diameter .032" x Length 150cm Type: Fixed Core Config: BENTSON Coating: PTFE
395933C	Diameter .038" x Length 150cm Type: Fixed Core Config: BENTSON Coating: PTFE
388300	Diameter .035" x Length 150cm Type: Movable Core Config: 3J Coating: PTFE
395309	Diameter .032" x Length 150cm Type: Movable Core Config: 3J Coating: PTFE
395315	Diameter .038" x Length 150cm Type: Movable Core Config: 3J Coating: PTFE
395320	Diameter .035" x Length 150cm Type: Movable Core Config: 3J Coating: PTFE
395330	Diameter .038" x Length 260cm Type: Movable Core Config: 3J Coating: PTFE
395337	Diameter .035" x Length 125cm Type: Movable Core Config: 6J Coating: PTFE

First Issued: **2024-06-17**

Date: **2024-06-17**

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

...making excellence a habit.™

UKCA Design-Examination Certificate

Supplementary Information to UKCA 759765

Issued To:

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

Catalogue Number	Model, Type
395398	Diameter .035" x Length 150cm Type: Movable Core Config: 1.5J Coating: PTFE
395656	Diameter .035" x Length 200cm Type: Movable Core Config: 3J Coating: PTFE
390282	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/XTB Coating: PTFE
390182	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/XTB/Z Coating: PTFE
390186	Diameter .035" x Length 175cm Type: Fixed Core Config: 3J/XTB/Z Coating: PTFE
390284	Diameter .038" x Length 150cm Type: Fixed Core Config: 3J/XTB/Z Coating: PTFE
393182	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/HD/Z Coating: PTFE
393184	Diameter .038" x Length 150cm Type: Fixed Core Config: 3J/HD/Z Coating: PTFE
393186	Diameter .035" x Length 175cm Type: Fixed Core Config: 3J/HD/Z Coating: PTFE
393187	Diameter .038" x Length 175cm Type: Fixed Core Config: 3J/HD/Z Coating: PTFE
393282	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/Z Coating: PTFE
395073	Diameter .035" x Length 260cm Type: Fixed Core Config: ST/HD Mullins Coating: PTFE
393999	Diameter .035" x Length 180cm Type: Fixed Core Config: DE-3J&ST Coating: PTFE
395112	Diameter .035" x Length 150cm Type: Fixed Core Config: DE-3J&ST Coating: PTFE
395205	Diameter .021" x Length 125cm Type: Fixed Core Config: ST

First Issued: **2024-06-17**

Date: **2024-06-17**

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

...making excellence a habit.™

UKCA Design-Examination Certificate

Supplementary Information to UKCA 759765

Issued To:

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

Catalogue Number	Model, Type
395208	Diameter .025" x Length 125cm Type: Fixed Core Config: ST
395212	Diameter .032" x Length 150cm Type: Fixed Core Config: ST
395509	Diameter .021" x Length 150cm Type: Fixed Core Config: ST
395224	Diameter .025" x Length 125cm Type: Fixed Core Config: ST Coating: PTFE
395225	Diameter .025" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE
395228	Diameter .032" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE
395231	Diameter .035" x Length 150cm Type: Fixed Core Config: ST Coating PTFE
395234	Diameter .038" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE
395367	Diameter .025" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE
395368	Diameter .032" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE
395369	Diameter .035" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE
395370	Diameter .038" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE
395457	Diameter .018" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE
395469	Diameter .018" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE
395501	Diameter .021" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE

First Issued: **2024-06-17**

Date: **2024-06-17**

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

...making excellence a habit.™

UKCA Design-Examination Certificate

Supplementary Information to UKCA 759765

Issued To:

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

Catalogue Number	Model, Type
395504	Diameter .021" x Length 125cm Type: Fixed Core Config: ST Coating: PTFE
395522	Diameter .021" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE
395703	Diameter .035" x Length 200cm Type: Fixed Core Config: ST Coating: PTFE
395884	Diameter .028" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE
A395231	Diameter .035" x Length 150cm Type: Fixed Core Config: ST Coating: PTFE
A395369	Diameter .035" x Length 260cm Type: Fixed Core Config: ST Coating: PTFE
388301	Diameter .035" x Length 150cm Type: Movable Core Config: ST Coating: PTFE
395258	Diameter .035" x Length 150cm Type: Movable Core Config: ST Coating: PTFE
395261	Diameter .038" x Length 150cm Type: Movable Core Config: ST Coating: PTFE
395333	Diameter .038" x Length 260cm Type: Movable Cable Config: ST Coating: PTFE
395280	Diameter .035" x Length 150cm Type: Fixed Core Config: 1.5J/HD Coating: PTFE
395332	Diameter .032" x Length 150cm Type: Fixed Core Config: 3J/HD Coating: PTFE
395350	Diameter .035" x Length 180cm Type: Fixed Core Config: 1.5J/HD Coating: PTFE
395993	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/HD Coating: PTFE
395266	Diameter .038" x Length 150cm Type: Movable Core Config: 3J/HD Coating: PTFE

First Issued: **2024-06-17**

Date: **2024-06-17**

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

...making excellence a habit.™

UKCA Design-Examination Certificate

Supplementary Information to UKCA 759765

Issued To:

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

Catalogue Number	Model, Type
395312	Diameter .035" x Length 150cm Type: Movable Core Config: 3J/HD Coating: PTFE
A395312	Diameter .035" x Length 150cm Type: Movable Core Config: 3J/HD Coating: PTFE
395919	Diameter .035" x Length 150cm Type: Fixed Core Config: DE/LT&1.5J Coating: PTFE
395345	Diameter .035" x Length 150cm Type: Fixed Core Config: DE-3J< Coating: PTFE
395352	Diameter .035" x Length 150cm Type: Fixed Core Config: 15J/LT Coating: PTFE
395382	Diameter .035" x Length 150cm Type: Fixed Core Config: LT Coating: PTFE
395384	Diameter .035" x Length 150cm Type: Fixed Core Config: LLT Coating: PTFE
395721	Diameter .035" x Length 145cm Type: Movable Core Config: LT/3J Coating: PTFE
395687	Diameter .035" x Length 150cm Type: Fixed Core Config: ST/HD Coating: PTFE
395708	Diameter .035" x Length 150cm Type: Fixed Core Config: 3J/LLT Coating: PTFE
395979	Diameter .015" x Length 150cm Type: Fixed Core Config: Mullins
395980	Diameter .017" x Length 150cm Type: Fixed Core Config: Mullins

First Issued: **2024-06-17**

Date: **2024-06-17**

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

...making excellence a habit.™

UKCA Design-Examination Certificate

Supplementary Information to UKCA 759765

Issued To:

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

Certificate History

Date	Reference Number	Action
Current	30110681	First Issue; Traceable to MDR 744230

First Issued: **2024-06-17**

Date: **2024-06-17**

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

...making excellence a habit.™