

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No.**CE 565721**

Issued To:

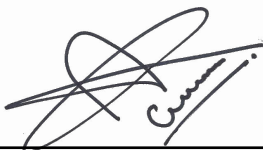
**Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens
Texas
75751
USA**

In respect of:

Stainless Steel and PTFE Coated Stainless Steel Guidewires

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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



Albert Roossien, Regulatory Lead

First Issued: **2011-02-28**Date: **2019-02-19**Expiry Date: **2022-12-01**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive 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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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Supplementary Information to CE 565721

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Product: Stainless Steel and PTFE Stainless Steel Coated Guidewires

Code	Product Description
388273	35/150/FC/SS/3J/CLASSIC
388275	38/150/FC/SS/3J/CLASSIC
388282	35/150/FC/PTFE/3J/CLASSIC
388284	38/150/FC/PTFE/3J/CLASSIC
388300	35/150/MC/PTFE/3J/CLASSIC
388301	35/150/MC/PTFE/ST/CLASSIC
388768	35/175/FC/PTFE/3J/CLASSIC
388794	35/260/FC/PTFE/3J/CLASSIC
390182	35/150/FC/PTFE/3J/XTB
390186	35/175/FC/PTFE/3J/XTB
390282	35/150/FC/PTFE/3J/XTB
390284	38/150/FC/PTFE/3J/XTB
393182	35/150/FC/PTFE/3J/EXT
393184	38/150/FC/PTFE/3J/EXT
393186	35/175/FC/PTFE/3J/EXT
393187	38/175/FC/PTFE/3J/HD/Z
393282	35/150/FC/PTFE/3J/EXT
393999	35/180/FC/PTFE/DE-3J&ST
395073	35/260/FC/PTFE/ST/MULLINS/HD
395112	35/150/FC/PTFE/DE/3J/ST

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395170	35/180/FC/PTFE/BEN
395183	35/150/FC/PTFE/3J/CLASSIC
395205	21/125/FC/SS/ST
395208	25/125/FC/SS/ST
395212	32/150/FC/SS/ST
395224	25/125/FC/PTFE/ST
395225	25/150/FC/PTFE/ST
395228	32/150/FC/PTFE/ST
395231	35/150/FC/PTFE/ST
395234	38/150/FC/PTFE/ST
395258	35/150/MC/PTFE
395261	38/150/MC/PTFE
395266	38/150/MC/PTFE/3J/HD
395270	25/125/FC/SS/3J
395273	35/150/FC/SS/3J
395275	38/150/FC/SS/3J
395279	25/125/FC/PTFE/3J
395280	35/150/FC/PTFE/1.5J/HD
395281	35/125/FC/PTFE/3J
395282	35/150/FC/PTFE/3J
395284	38/150/FC/PTFE/3J
395289	35/150/FC/PTFE/6J
395309	32/150/MC/PTFE/3J
395312	35/150/MC/PTFE/3J
395315	38/150/MC/PTFE/3J
395320	35/150/MC/PTFE/3J/SLIP
395330	38/260/MC/PTFE/3J

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395332	32/150/FC/PTFE/3J/HD
395333	38/260/MC/PTFE/STRAIGHT
395337	35/125/MC/PTFE/6J
395345	35/150/FC/PTFE/DE/3J/LT
395350	35/180/FC/PTFE/1.5J/HD
395352	35/150/FC/PTFE/15J/LT
395367	25/260/FC/PTFE/ST
395368	32/260/FC/PTFE/ST
395369	35/260/FC/PTFE/ST
395370	38/260/FC/PTFE/ST
395382	35/150/FC/PTFE/LT
395384	35/150/FC/PTFE/LLT
395398	35/150/MC/PTFE/1.5J
395406	21/260/FC/PTFE/3J
395420	25/150/FC/PTFE/1.5J
395457	18/150/FC/PTFE/ST
395465	18/150/FC/PTFE/3J
395469	18/260/FC/PTFE/ST
395470	18/150/FC/PTFE/1.5J
395501	21/150/FC/PTFE/ST
395504	21/125/FC/PTFE/ST
395509	21/150/FC/SS/ST
395522	21/260/FC/PTFE/ST
395523	21/150/FC/PTFE/3J
395559	25/150/FC/PTFE/3J
395585	25/260/FC/PTFE/3J
395600	32/150/FC/PTFE/3J

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395603	32/150/FC/SS/3J
395613	32/125/FC/PTFE/3J
395622	32/260/FC/PTFE/3J
395656	35/200/MC/PTFE/3J
395687	35/150/FC/PTFE/HD/ST
395703	35/200/FC/PTFE/ST
395708	35/150/FC/PTFE/3J/LLT
395721	35/145/MC/PTFE/LT/3J
395722	35/200/FC/PTFE/3J
395768	35/175/FC/PTFE/3J
395780	35/150/FC/PTFE/7.5J
395787	35/150/FC/PTFE/1.5J
395794	35/260/FC/PTFE/3J
395817	38/200/FC/PTFE/3J
395839	38/260/FC/PTFE/3J
395863	38/150/FC/PTFE/1.5J
395884	28/150/FC/PTFE/ST
395900	32/150/FC/PTFE/1.5J
395919	35/150/FC/PTFE/LT/1.5J
395930E	35/150/FC/PTFE/BEN
395931	32/150/FC/PTFE/BEN
395933C	38/150/FC/PTFE/BEN
395961	28/150/FC/PTFE/3J
395979	15/150/FC/SS/MULLINS
395980	17/150/FC/SS/MULLINS
395991	30/150/FC/PTFE/3J
395993	35/150/FC/PTFE/3J/HD

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A395231	35/150/FC/PTFE/CLASSIC
A395282	35/150/FC/PTFE/3J
A395284	38/150/FC/PTFE/3J
A395312	35/150/MC/PTFE/3J/HD
A395369	35/260/FC/PTFE/CLASSIC
A395482	35/180/FC/PTFE/3J
A395559	25/150/FC/PTFE/3J
A395600	32/150/FC/PTFE/3J
A395613	32/125/FC/PTFE/3J
A395722	35/200/FC/PTFE/3J
A395787	35/150/FC/PTFE/1.5J
A395900	32/150/FC/PTFE/1.5J

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Certificate History

Date	Reference Number	Action
28 February 2011	10118188	First Issue – Transfer from another Notified Body.
03 December 2012	10137338	Certificate renewal.
13 March 2013	10139964	Introduction of new coating material and removal of obsolete product codes.
11 July 2014	10146973	Introduction of new coating material and removal of obsolete product code. Shelf life extension for the PTFE Coated Stainless Steel Guidewires from 2 to 5 years.
23 November 2015	10159122	Addition of the Sterigenics location in Grand Prairie, TX as a sterilization location. Add the product code 395333 to the product list, as this code was inadvertently omitted from the certificate at the time of transfer. Replace product code 395930 with 395390E and product code 395933 with 395933C, as the suffixes for these codes were inadvertently omitted during the transfer.
11 January 2018	8847353	Certificate renewal. Removal of 395209 and 395353 product codes.
Current	7780687	Traceable to NB 0086.

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