EC Design-Examination Certificate

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

No. **CE 504490**

Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

In respect of:

Cerebral and Myocardial Embolic Protection Devices:

Emboshield NAV6 and Associated Filter Delivery Wires.

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):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2006-03-10** Date: **2020-04-03** Expiry Date: **2024-05-26**

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
22442-19	Emboshield NAV^6 Embolic Protection System	Small	The system is designed to reduce distal embolization while maintaining blood flow during interventional procedures. The system is indicated for use during percutaneous transluminal angioplasty, and stenting procedures in saphenous vein grafts and carotid arteries and percutaneous transluminal angioplasty, atherectomy and stenting procedures in the lower extremity arteries.	Class III
22443-19	Emboshield NAV^6 Embolic Protection System	Large		
22444-19	BareWire Distal Access Filter Delivery Wire	190cm		
22445-19	BareWire Workhorse Filter Delivery Wire	190cm		
22445-31	BareWire Workhorse Filter Delivery Wire	315cm		
22446-19	BareWire Support Filter Delivery Wire	190cm		

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Certificate History

Date	Reference Number	Action
10 March 2006	10077732	Transfer from another Notified Body.
04 May 2006	10078764	The name of the product has been changed to Emboshield® PRO. Changes to the design of the filtration element frame assembly and filter assembly. Changes were also made to the delivery catheter, loading funnel, loading tool, retrieval catheter and the packaging.
07 September 2006	10080978	Shelf-life increased to 2 years.
29 June 2007	10088792	Change to model numbers: "54" deleted from all model numbers. Remove the word 'vascular' and replace with 'embolic' in the scope.
08 August 2007	10090953	Change in FEP materials for Emboshield® PRO.
21 December 2007	10092642	Change in lubricant from a different supplier.
23 September 2008	10098163	Add new product: Emboshield Nav^6 Embolic Protection System and BareWire Filter Delivery Wires. Change the Legal Manufacturer to the Abbott Vascular, Vascular Solutions.
20 February 2009	10102942	Remove Business Unit name (Vascular Solutions) from the certificate.
31 March 2009	10104629	Update to change the sterilization site to Sterigenics, CA, change to the manufacturing location from Abbott Ireland Vascular Division in Galway, Ireland to Abbott Vascular, Temecula, CA and review of minor process improvements and packaging pouch material change.

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Date	Reference Number	Action
28 February 2011	10121511	Certificate Renewal for a five-year period. Removal of the Emboshield PRO catalogue codes 82904-19, 82904/31, 82905-19 and 82905-31 as that product family has been discontinued.
21 April 2011	10123617	Changing hydrophilic coating on the Filtration Element.
05 July 2012	10135940	Change of the adhesive to bond the radiopaque marker band on the delivery catheter for the Emboshield Nav^6 – Embolic Protection System.
26 November 2014	10152576	Change of the BareWire Filter Delivery Wire coating to a PFOA-Free formulation.
13 November 2015	10158210	Introduction of electronic IFUs in compliance with Regulation 207/2012.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project Update.
19 February 2016	10161520	Certificate Renewal.
21 October 2016	10166067	Addition of Sterigenics in Costa Rica as a significant subcontractor for ETO sterilization.

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Date	Reference Number	Action
27 February 2019	7780598	Traceable to NB 0086.
21 November 2019	9753946	Certificate Renewal. Administrative update to product table format.
Current	9767473	Certificate change: intended use statement expanded to include use in lower extremity arteries. Multiple update to IFU including device description, instructions for preparation and deployment, contraindications, warnings and precaution sections.

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