By Royal Charter

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 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **10 March 2006** Date: **19 February 2016** Expiry Date: **09 March 2021**

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Emboshield NAV 6 Embolic Protection System:

Catalogue Numbers	Filtration Element Size	Intended Vessel Diameter (mm)	Filter Delivery Wire Length (cm)
22442 - 19	Small	2.5-4.8	190
22443 - 19	Large	4.0-7.0	190

BareWire Filter Delivery Wires:

Catalogue Numbers	Filter Delivery Wire Support	Filter Delivery Wire Length(cm)
22444-19	Distal Access	190
22445-19	Workhorse	190
22445-31	Workhorse	315
22446-19	Support	190

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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	10080979	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.

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Date	Reference Number	Action
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.
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 NAV6 – 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.

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Date	Reference Number	Action
19 February 2016	10161520	Certificate renewal.

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