

DECLARATION OF CONFORMITY

Manufacturer: Abbott Vascular

Address: 3200 Lakeside Drive
Santa Clara, California 95054, USA

**Additional
Manufacturing Sites:
(as appropriate)** 26531 Ynez Road
Temecula, CA 92591, USA

Device Name: **Emboshield NAV⁶ Embolic Protection System &
Bare Wire Filter Delivery Wires**

Device Classification: Class III

GMDN Code: 44841: emboli capture guidewires
58115 : peripheral vascular guidewire

Classification Rationale: The following Annex IX definition(s) apply to the **Emboshield NAV⁶ Embolic Protection System & Bare Wire Filter Delivery Wires** for purposes of classification: Per Rule 6, Annex IX, all surgically invasive devices intended for transient use are in Class IIa unless they are: intended specifically to control, diagnose, monitor, or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III.

**Authorized European
Representative:** Abbott Vascular International BVBA
Park Lane
Culliganlaan 2B
1831 Diegem, Belgium

Model Numbers: Emboshield NAV⁶ Embolic Protection System

Description (diameter, system length)	Part Number
Emboshield NAV6, Small, 2.5 – 4.8mm, 190 cm	22442-19
Emboshield NAV6, Large, 4.0 – 7.0mm, 190 cm	22443-19

Model Numbers: Bare Wire Filter Delivery Wires

Description	Part Number
Bare Wire FDW, Distal Access, 190 cm	22444-19
Bare Wire FDW, Workhorse, 190 cm	22445-19
Bare Wire FDW, Workhorse, 315 cm	22445-31
Bare Wire FDW, Support, 190 cm	22446-19

I, the undersigned, hereby declare that the medical devices specified above conform with the applicable Essential Requirements listed in Annex I and Annex II of EC Council Directive 93/42/EEC.

Directive 2006/42/EC on Machinery and directive 89/686/EEC on Personal Protective Equipment do not apply.

This declaration is supported by the EC Quality System (Annex II) and design examination certification listed below.

Supporting Certificates:

EC Quality Management System – EN ISO 13485:2003

Certificate Number: FM72377

EC Design Examination Certificate Number: CE 504490

Annex II Certificate Number: CE 510108

Notified Body: British Standards Institution (0086)
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MK5 8PP
United Kingdom

This Declaration of Conformity is valid until revision, or with the obsolescence of the supporting Annex II and EC Design Examination certificates listed above.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Authorized Signatory:  Feb. 21, 2016
Sam Huang, Regulatory Affairs Specialist

Issued By:  Date: February 23rd, 2016
Susan Slane 
Divisional VP, Global Quality and Compliance
Abbott Vascular

Place of issue: Venecula, CA, USA Date of issue: February 23rd, 2016

Effective Date: February 23rd, 2016