

3200 Lakeside Drive Santa Clara, CA 95054

Tel 408-845-3000 Fax 408-845-3333

## **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 NAV<sup>6</sup> 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 NAV<sup>6</sup> 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 NAV<sup>6</sup> 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

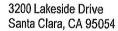
EC Design Examination Certificate Number: CE 504490

Annex II Certificate Number: CE 510108

Notified Body: British Standards Institution (0086)

Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP

United Kingdom





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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:  Sam Huang, Regulatory Affairs Specialist  Feb. 21, 2016
Issued By: N. Later Date: Telmany 23.1, 2016 Susan Slane J. Knoter Divisional VP, Global Quality and Compliance Abbott Vascular
Place of issue: Venscula, CA. USA Date of issue: February 23 2016
Effective Date: February 23rd, 2016