



Tel: 408-845-3000 Fax: 408-845-3743

## DECLARATION OF CONFORMITY

**Manufacturer:** Abbott Vascular

Address: 3200 Lakeside Drive

Santa Clara, CA 95054

**USA** 

**Manufacturing Sites:** 26531 Ynez Road

Temecula, CA 92591

**USA** 

Emboshield NAV<sup>6</sup> Embolic Protection System and **Device Name:** 

BareWire Filter Delivery Wires

**Device Classification:** Class III

**GMDN Code:** 44841 emboli capture guidewire

58115 peripheral vascular guidewire, manual

**Classification Rationale:** The following Annex IX definition(s) apply to the

> Emboshield NAV<sup>6</sup> Embolic Protection System and 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** 

Abbott Vascular International BVBA

Park Lane, Culliganlaan 2B **Representative:** 



Tel: 408-845-3000 Fax: 408-845-3743

## **Model Number:** Emboshield NAV<sup>6</sup> Embolic Protection System

<b>Description</b> (diameter, system length)	Part Number
Emboshield NAV <sup>6</sup> Embolic Protection System, Small, 2.5 – 4.8mm, 190 cm	22442-19
Emboshield NAV <sup>6</sup> Embolic Protection System, Large, 4.0 – 7.0mm, 190 cm	22443-19

## **Model Number:** BareWire Filter Delivery Wires

Description	Part Number
BareWire Distal Access Filter Delivery Wire, 190 cm	22444-19
BareWire Workhorse Filter Delivery Wire, 190 cm	22445-19
BareWire Workhorse Filter Delivery Wire, 315 cm	22445-31
BareWire Support Filter Delivery Wire, 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, ISO 13485:2016 Certificate Number: FM 72377

EC Design Examination Certificate: CE 504490

Annex II Certificate Number: CE 510108

Notified Body: BSI Group The Netherlands B.V. (2797)

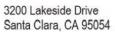
Say Building

John M. Keynesplein 9

Netherlands

1066 EP Amsterdam

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





Tel: 408-845-3000 Fax: 408-845-3743

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

Authorized Signatory: _ Namratha Manthani, Manager, Regulatory At Abbott Vascular	Date:	
Issued By: Pauline Hanley Sr. Director, Quality Op Abbott Vascular	Date:	
Place of issue:	Date of issue:	
Effective Date:		



3200 Lakeside Drive Santa Clara, CA 95054

Tel 408-845-3000 Fax: 408-845-3743

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

Namratha Manthani, Manager, Regulatory A	Maukaw	Date:	201C)
Sr. Director, Quality Of	e Coully peration and Compliance	Date: 26 - May	-2020
Abbott Vascular  Place of issue:	ounel	Date of issue:_/	Maj 26th 2020
Effective Date: 18th	May 2020		