3200 Lakeside Drive
Santa Clara, CA 95054

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
Device Name:	Emboshield NAV^6 Embolic Protection System and 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^6 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 Representative:	Abbott Vascular International BVBA Park Lane, Culliganlaan 2B 1831 Diegem, Belgium

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Model Number: Emboshield NAV^6 Embolic Protection System

Description (diameter, system length)	**Part Number**
Emboshield NAV^6 Embolic Protection System, Small, 2.5 – 4.8mm, 190 cm	22442-19
Emboshield NAV^6 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.

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

Authorized Signatory: Nmanthaw Date: 18-May-2020
Namratha Manthani,
Manager, Regulatory Affairs
Abbott Vascular

Issued By: _____ Date: _____
Pauline Hanley
Sr. Director, Quality Operation and Compliance
Abbott Vascular

Place of issue: _____ Date of issue: _____

Effective Date: _____

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Authorized Signatory: Namratha Date: 18-May-2020
Namratha Manthani,
Manager, Regulatory Affairs
Abbott Vascular

Issued By: Pauline Hanley Date: 26-May-2020
Pauline Hanley
Sr. Director, Quality Operation and Compliance
Abbott Vascular

Place of issue: Clonmel Date of issue: May 26th 2020

Effective Date: 18th May 2020