Abbott Vascular

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:	26531 Ynez Road Temecula, California 92591, USA
Device Name:	**RX ACCUNET Embolic Protection System**
Device Classification:	Class III
GMDN Code:	44841: embolic capture guidewires
Classification Rationale:	The following Annex IX definition(s) apply to the RX ACCUNET Embolic Protection System 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 Numbers: **RX ACCUNET Embolic Protection System**

Description (diameter, system length)	**Part Number**
RX ACCUNET, 4.5 mm, 190 cm	1010134-45
RX ACCUNET, 5.5 mm, 190 cm	1010134-55
RX ACCUNET, 6.5 mm, 190 cm	1010134-65
RX ACCUNET, 7.5 mm, 190 cm	1010134-75
RX ACCUNET, 4.5 mm, 300 cm	1010135-45
RX ACCUNET, 5.5 mm, 300 cm	1010135-55
RX ACCUNET, 6.5 mm, 300 cm	1010135-65
RX ACCUNET, 7.5 mm, 300 cm	1010135-75
RX ACCUNET (3:1), 4.5 mm, 190 cm	1011651-45
RX ACCUNET (3:1), 5.5 mm, 190 cm	1011651-55
RX ACCUNET (3:1), 6.5 mm, 190 cm	1011651-65
RX ACCUNET (3:1), 7.5 mm, 190 cm	1011651-75
RX ACCUNET (3:1), 4.5 mm, 300 cm	1011652-45
RX ACCUNET (3:1), 5.5 mm, 300 cm	1011652-55
RX ACCUNET (3:1), 6.5 mm, 300 cm	1011652-65
RX ACCUNET (3:1), 7.5 mm, 300 cm	1011652-75

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 approval listed below.

Supporting Certificates:
EC Quality Management System – EN ISO 13485:2003,
Certificate Number: FM72377
EC Design Examination Certificate Number: CE 518026
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: _____ 1/15/2016
Sam Huang, Regulatory Affairs Specialist

Issued By: _____ Date: 1/15/2016
Susan Slane
Divisional VP, Global Quality and Compliance
Abbott Vascular

Place of issue: Temecula Date of issue: 1/15/2016

Effective Date: 1/15/2016