

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



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

Model Numbers:	RX ACCUNET Embolic Protection System
----------------	--------------------------------------

Description Description	Part
(diameter, system length)	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

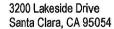
Notified Body: British Standards Institution (0086)

Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP

United Kingdom

Version 5.0 January 15, 2016

Page 2 of 3





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

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
built Hading, Regulatory Milans Specialist
Issued By: Date: 1/15/20/6
Susan Slane //
Divisional VP, Global Quality and Compliance
Abbott Vascular
1 1 1 - 1 - 11
Place of issue: 1/15/2016
Titod of Issue, The Color Button Issue, The Color Butt
Esserting Date: 1/15/2016
Effective Date: /// 0/ CO/ O