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 ACCULINK Carotid Stent System**
Device Classification:	Class III
GMDN Code:	45851 : stent, vascular, carotid
Classification Rationale:	The following Annex IX definition(s) apply to the RX ACCULINK Carotid Stent Systems for purposes of classification: Per Rule 8, Annex IX, all implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended: to be used in direct contact with the heart, the central circulatory system, or the central nervous system, in which case they are in Class III.
Authorized European Representative:	Abbott Vascular International BVBA Park Lane Culliganlaan 2B 1831 Diegem, Belgium

Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 95054

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

Model Numbers: **RX ACCULINK Carotid Stent System**

Description (stent diameter, system length)	Configuration	Part Number	Suffix -XX (stent length, mm)		
RX ACCULINK 5.0mm, 135cm	Straight	1010126	-20	-30	-40
RX ACCULINK 6.0mm, 135cm	Straight	1010127	-20	-30	-40
RX ACCULINK 7.0mm, 135cm	Straight	1010128	-20	-30	-40
RX ACCULINK 8.0mm, 135cm	Straight	1010129	-20	-30	-40
RX ACCULINK 9.0mm, 135cm	Straight	1010130	-20	-30	-40
RX ACCULINK 10.0mm, 135cm	Straight	1010131	-20	-30	-40
RX ACCULINK 6-8mm, 135cm	Tapered	1010132	NA	-30	-40
RX ACCULINK 7-10mm, 135cm	Tapered	1010133	NA	-30	-40

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 518027
Annex II Certificate Number: CE 510108

Notified Body: British Standards Institution (0086)
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes
MK5 8PP
United Kingdom

Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 95054

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: _____ 1/15/2016
Sam Huang, Regulatory Affairs Specialist
Abbott Vascular

Issued By: _____
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