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 Cashel Road Clonmel, County Tipperary, Ireland
Device Name:	**RX HERCULINK ELITE Peripheral Stent System**
Device Classification:	Class IIb
GMDN Code:	47932 - Multiple peripheral artery stent
Classification Rationale:	The following Annex IX definition(s) apply to the **RX HERCULINK ELITE Peripheral Stent System** 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

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Model Numbers: RX HERCULINK® ELITE™ Peripheral Stent System

Description (stent diameter, system length)	Part Number	Suffix -XX (stent length, mm)		
RX HERCULINK ELITE 4.0mm, 80cm	1011521	-12	-15	-18
RX HERCULINK ELITE 4.0mm, 135cm	1011522	-12	-15	-18
RX HERCULINK ELITE 4.5mm, 80cm	1011524	-12	-15	-18
RX HERCULINK ELITE 4.5mm, 135cm	1011525	-12	-15	-18
RX HERCULINK ELITE 5.0mm, 80cm	1011527	-12	-15	-18
RX HERCULINK ELITE 5.0mm, 135cm	1011528	-12	-15	-18
RX HERCULINK ELITE 5.5mm, 80cm	1011530	-12	-15	-18
RX HERCULINK ELITE 5.5mm, 135cm	1011531	-12	-15	-18
RX HERCULINK ELITE 6.0mm, 80cm	1011533	-12	-15	-18
RX HERCULINK ELITE 6.0mm, 135cm	1011534	-12	-15	-18
RX HERCULINK ELITE 6.5mm, 80cm	1011536	-12	-15	-18
RX HERCULINK ELITE 6.5mm, 135cm	1011537	-12	-15	-18
RX HERCULINK ELITE 7.0mm, 80cm	1011539	NA	-15	-18
RX HERCULINK ELITE 7.0mm, 135cm	1011540	NA	-15	-18

I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I and Annex II (except Part 4) of EC Council Directive 93/42/EEC.

Directive 2006/42/EC on Machinery and Directive 89/686/EC on Personal Protective Equipment do not apply.

This declaration is supported by an EC quality system certification listed below.

Supporting Certificates:
EC Quality Management System, ISO 13485:2003 Certificate Number: FM 72377
Annex II Certificate Number: CE 510108

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

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This Declaration of Conformity is valid until its revision or with the obsolescence of the supporting Annex II certificate listed above.

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

Authorized Signatory: _____
Aruna Akkapeddi, Sr. RA Specialist

Issued By: J. Kratek for S. Slane
Susan Slane, Divisional VP, Global Quality & Compliance
Abbott Vascular J. Kratek

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.
Place of issue: Temecula, CA. USA Date of issue: February 23rd, 2016

Effective Date: February 23rd, 2016

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Delegation Memo Template

Signature Delegation requirements are listed in DOP5852.

This memo delegates my signature authority to: Jim Krater

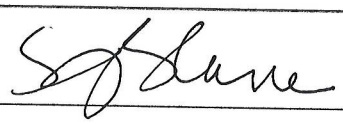
Scope of delegation authority includes: Full authority for Finance, HR and Quality and Compliance signature requirements.

Delegation begins on: 22 February, 2016

Delegation ends on: 02 March, 2016

Name: Susan Slane

Title: DVP, Global Quality and Compliance

Signature: 

Date: 19 February, 2016

Attach this evidence of delegation to all records being approved.