Abbott Vascular

3200 Lakeside Drive
Santa Clara, CA 94086

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 VIATRAC® 14 PLUS** **Peripheral Dilatation Catheter**
Device Classification:	Class IIa
Classification Rationale:	The following Annex IX definition(s) apply to the RX VIATRAC® 14 PLUS Peripheral Dilatation Catheter 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 VIATRAC® 14 PLUS Peripheral Dilatation Catheter**

Description (balloon diameter, system length)	**Part Number**	**Suffix -XX** (balloon length, mm)			
RX VIATRAC 14 PLUS 4.0mm, 80cm	1008190	-15	-20	-30	-40
RX VIATRAC 14 PLUS 4.0mm, 135cm	1008189	-15	-20	-30	-40
RX VIATRAC 14 PLUS 4.5mm, 80cm	1008192	-15	-20	-30	-40
RX VIATRAC 14 PLUS 4.5mm, 135cm	1008191	-15	-20	-30	-40
RX VIATRAC 14 PLUS 5.0mm, 80cm	1008194	-15	-20	-30	-40
RX VIATRAC 14 PLUS 5.0mm, 135cm	1008193	-15	-20	-30	-40
RX VIATRAC 14 PLUS 5.5mm, 80cm	1008196	-15	-20	-30	-40
RX VIATRAC 14 PLUS 5.5mm, 135cm	1008195	-15	-20	-30	-40
RX VIATRAC 14 PLUS 6.0mm, 80cm	1008198	-15	-20	-30	-40
RX VIATRAC 14 PLUS 6.0mm, 135cm	1008197	-15	-20	-30	-40
RX VIATRAC 14 PLUS 6.5mm, 80cm	1008200	-15	-20	-30	-40
RX VIATRAC 14 PLUS 6.5mm, 135cm	1008199	-15	-20	-30	-40
RX VIATRAC 14 PLUS 7.0mm, 80cm	1008202	-15	-20	-30	-40
RX VIATRAC 14 PLUS 7.0mm, 135cm	1008201	-15	-20	-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 Part 4 of EC Council Directive 93/42/EEC.

This declaration is supported by an EC quality system and design examination approval (Annex II) under the supervision of the British Standards Institution, a notified body authorized by the United Kingdom Competent Authority. (EC Quality System Certificate Number CE 510108).

By: SG Slane Date: 5/24/10

Susan Slane
Divisional VP, Quality, Compliance, and Analytical Chemistry
Abbott Vascular