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:	**HI-TORQUE SPARTACORE® 14 Guide Wire**
Device Classification:	Class III
Classification Rationale:	The following Annex IX definition(s) apply to the HI-TORQUE SPARTACORE® 14 Guide Wire 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: **HI-TORQUE SPARTACORE® 14 Guide Wire**

Description	Part Number
HI-TORQUE SPARTACORE 14, 5cm, 130 cm	1005201
HI-TORQUE SPARTACORE 14, 5cm, 190 cm	1005202
HI-TORQUE SPARTACORE 14, 5cm, 300 cm	1005203
HI-TORQUE SPARTACORE 14, 10cm, 130 cm	1005204
HI-TORQUE SPARTACORE 14, 10cm, 190 cm	1005205
HI-TORQUE SPARTACORE 14, 10cm, 300 cm	1005206

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; EC Certificate Number CE 518028).

By: Susan Slane Date: 5/24/10

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