

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 STEELCORE™ 18 Guide Wire**
HI-TORQUE STEELCORE™ 18 LT Guide Wire

Device Classification: Class III

Classification Rationale: The following Annex IX definition(s) apply to the HI-TORQUE STEELCORE™ 18 and HI-TORQUE STEELCORE™ 18 LT Guide Wires 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

Model Numbers: HI-TORQUE STEELCORE™ 18 Guide Wire

Description	Part Number
HI-TORQUE STEELCORE 18, 130 cm	1003280
HI-TORQUE STEELCORE 18, 190 cm	1003281
HI-TORQUE STEELCORE 18, 300 cm	1003282

HI-TORQUE STEELCORE™ 18 LT Guide Wire

Description	Part Number
HI-TORQUE STEELCORE 18 LT, 130 cm	1007708
HI-TORQUE STEELCORE 18 LT, 190 cm	1007709
HI-TORQUE STEELCORE 18 LT, 300 cm	1007710
HI-TORQUE STEELCORE 18 LT, J, 130 cm	1007708-J
HI-TORQUE STEELCORE 18 LT, J, 190 cm	1007709-J
HI-TORQUE STEELCORE 18 LT, J, 300 cm	1007710-J

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