

DECLARATION OF CONFORMITY

Manufacturer: Abbott Vascular

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Cruce Davilla
Barceloneta 00617, Puerto Rico

Device Name: HI-TORQUE® BALANCE HEAVYWEIGHT™ 0.014”
Guide Wire with Hydrocoat Hydrophilic Coating

Device Classification: Class III

GMDN Code: 35094, Catheter guide wire

Classification Rationale: The following Annex IX definition(s) apply to the HI-TORQUE® BALANCE HEAVYWEIGHT™ 0.014”
Guide Wire with Hydrocoat Hydrophilic Coating for purposes of classifications: 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.

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