

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

Building PR-17, Road #2 km. 58.0
Cruce Davilla
Barceloneta 00617, Puerto Rico

Device Name: HI-TORQUE BALANCE MIDDLEWEIGHT
UNIVERSAL II Guide Wire

Device Classification: Class III

GMDN Code: 35094, Catheter guide wire

Classification Rationale: The following Annex IX definition(s) apply to the
HI-TORQUE BALANCE MIDDLEWEIGHT
UNIVERSAL II Guide Wire 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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