



ABBOTT VASCULAR

3200 Lakeside Drive
Santa Clara, CA 95054

T: 408 845 3000
F: 408 845 3743

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, Cardiac guidewire, single-use

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. Per Rule 7, Annex IX, all surgically invasive devices intended for short-term use are in Class IIa unless they are intended - either 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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**Authorized European
Representative:**

Abbott Vascular International BVBA
Park Lane, Culliganlaan 2B
1831 Diegem, Belgium

Model Numbers:

HI-TORQUE BALANCE MIDDLEWEIGHT
UNIVERSAL II™ Guide Wire

1009664	1009664J
1009665	1009665J
1009666	1009666J
1009667	1009667J

I, the undersigned, hereby declare that the medical devices specified above conform with the applicable *Essential Requirements* listed in Annex I and Annex II of EC Council Directive 93/42/EEC.

Directive 2006/42/EC on Machinery and directive 89/686/EEC on Personal Protective Equipment do not apply.

This declaration is supported by an EC quality system (Annex II) and design examination certification listed below.

Supporting Certificates:

EC Quality Management System - ISO 13485:2016,

Certificate Number: FM72377, FM510125

EC Design Examination Certificate Number: CE 534263

Annex II Certificate Number: CE 510108

Notified Body: British Standards Institution, a notified body authorized by the Dutch Competent Authority, Notified Body Identification Number 2797.

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands

This Declaration of Conformity is valid until its revision, or with the obsolescence of the supporting Annex II and EC Design Examination certificates listed above.

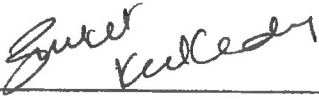


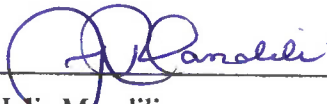
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This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Authorized
Signatory: 
Aniket Khakhadiya
Senior Specialist, Regulatory Affairs
Abbott Vascular

Issued By: 
Julie Manalili,
Senior Director Quality, Operations and Compliance
Abbott Vascular

Place of issue: Temecula

Date of issue: 22 Jul - 2019

Effective Date: 22 Jul - 2019