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<br>Santa Clara, California 95054, USA |
| **Additional Manufacturing Sites:** | 26531 Ynez Road<br>Temecula, California 92591, USA<br><br>Building PR-17, Road #2 km. 58.0<br>Cruce Davilla<br>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.<br>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