

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

Abbott Vascular Costa Rica
52 Calle 3, B31, Coyol Free Zone
El Coyol Alajuela, Costa Rica

Device Name: **TREK RX and MINI TREK RX,
TREK OTW and MINI TREK OTW
MINI TREK II OTW
Coronary Dilatation Catheters**

Device Classification: Class III

GMDN Code: 47732 - Basic Coronary Angioplasty Balloon Catheter

Classification Rationale: The following Annex IX definition(s) apply to the
**TREK RX and MINI TREK RX,
TREK OTW and MINI TREK OTW, and MINI TREK
II OTW Coronary Dilatation Catheters** 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.

**Authorized European
Representative:** Abbott Vascular International BVBA
Park Lane
Culliganlaan 2B
1831 Diegem, Belgium

Model Numbers: MINI TREK RX and TREK RX

MINI TREK RX Coronary Dilatation Catheters								
Balloon Diameter (mm)	Catalog Numbers	Balloon Length						
	Global	6mm	8mm	12mm	15mm	20mm	25mm	30mm
1.20	1012268	-06	-08	-12	-15	-20		
1.50	1012269	-06	-08	-12	-15	-20		
2.00	1012270	-06	-08	-12	-15	-20	-25	-30

TREK RX Coronary Dilatation Catheters								
Balloon Diameter (mm)	Catalog Numbers	Balloon Length						
	Global	6mm	8mm	12mm	15mm	20mm	25mm	30mm
2.25	1012271	-06	-08	-12	-15	-20	-25	-30
2.50	1012272	-06	-08	-12	-15	-20	-25	-30
2.75	1012273	-06	-08	-12	-15	-20	-25	-30
3.00	1012274	-06	-08	-12	-15	-20	-25	-30
3.25	1012275	-06	-08	-12	-15	-20	-25	-30
3.50	1012276	-06	-08	-12	-15	-20	-25	-30
3.75	1012277	-06	-08	-12	-15	-20	-25	-30
4.00	1012278	-06	-08	-12	-15	-20	-25	-30
4.50	1012279			-12	-15			
5.00	1012280			-12	-15			

Model Numbers: MINI TREK OTW and TREK OTW

MINI TREK OTW Coronary Dilatation Catheters								
Balloon Diameter (mm)	Catalog Numbers	Balloon Length						
	Global	6mm	8mm	12mm	15mm	20mm	25mm	30mm
1.20	1012401	-06	-08	-12	-15	-20		
1.50	1012402	-06	-08	-12	-15	-20		
2.00	1012403	-06	-08	-12	-15	-20	-25	-30

TREK OTW Coronary Dilatation Catheters								
Balloon Diameter (mm)	Catalog Numbers	Balloon Length						
	Global	6mm	8mm	12mm	15mm	20mm	25mm	30mm
2.25	1012404	-06	-08	-12	-15	-20	-25	-30
2.50	1012405	-06	-08	-12	-15	-20	-25	-30
2.75	1012406	-06	-08	-12	-15	-20	-25	-30
3.00	1012407	-06	-08	-12	-15	-20	-25	-30
3.25	1012408	-06	-08	-12	-15	-20	-25	-30
3.50	1012409	-06	-08	-12	-15	-20	-25	-30
3.75	1012410	-06	-08	-12	-15	-20	-25	-30
4.00	1012411	-06	-08	-12	-15	-20	-25	-30
4.50	1012412			-12	-15			
5.00	1012413			-12	-15			

Model Numbers: MINI TREK II OTW

MINI TREK II OTW Coronary Dilatation Catheters								
Balloon Diameter (mm)	Catalog Numbers	Balloon Length						
	Global	6mm	8mm	12mm	15mm	20mm	25mm	30mm
1.20	1012401	-06A	-08A	-12A	-15A	-20A		
1.50	1012402	-06A	-08A	-12A	-15A	-20A		
2.00	1012403	-06A	-08A	-12A	-15A	-20A		

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 1989/686/EC 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, EN ISO 13485:2003, Certificate Number:
FM72377

EC Design Examination: Certificate Number: CE 561260

Annex II Certificate Number: CE 510108

Notified Body:

British Standards Institution (BSi), Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP United Kingdom, Notified Body Identification Number 0086.

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

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

By: Susan Slane Date: 4/13/15

Susan Slane
Divisional VP, Global Quality and Compliance
Abbott Vascular