

# EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

**No.****CE 561260****Issued To:****Abbott Vascular  
3200 Lakeside Drive  
Santa Clara  
California  
95054  
USA**

In respect of:

**TREK and MINI TREK RX and OTW and MINI TREK II OTW Coronary Dilatation Catheters**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **20 April 2010**

Date: **12 January 2016**

Expiry Date: **19 April 2020**

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Page 1 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

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

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

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Page 2 of 7

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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
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MINI TREK OTW Coronary Dilatation Catheters Part Numbers								
Balloon Diameter (mm)	Catalog Numbers	Balloon Length						
	Global	6mm	8mm	12mm	15mm	20mm	25mm	30mm
<b>1.20</b>	1012401	-06	-08	-12	-15	-20		
<b>1.50</b>	1012402	-06	-08	-12	-15	-20		
<b>2.00</b>	1012403	-06	-08	-12	-15	-20	-25	-30

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Page 3 of 7

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

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Page 4 of 7

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

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Page 5 of 7

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## Certificate History

Date	Reference Number	Action
20 April 2010	10116016	First Issue - add TREK™ and MINI TREK™ RX Coronary Dilatation Catheters
29 September 2010	10117881	Addition of TREK™ OTW and MINI TREK™ OTW Coronary Dilatation Catheters
13 December 2011	10132271	Addition of manufacturing site in Alajuela, Costa Rica for TREK RX and MINI TREK RX (2.0mm size only)
05 April 2012	10134141	Addition of manufacturing site in Alajuela, Costa Rica for TREK OTW and MINI TREK OTW (2.0mm size only)
12 June 2012	10135733	Addition of manufacturing site in Alajuela, Costa Rica for MINI TREK RX and MINI TREK OTW (1.2 and 1.5mm sizes).
19 September 2012	10136492	Completion of the final phase of the Costa Rica manufacturing transfer to add the Abbott Vascular Costa Rica Main Building for all TREK and MINI TREK catalogue codes. Design change to strain relief for all TREK RX and MINI TREK RX catalogue codes. Removal of ™ symbol.

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Page 6 of 7

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Date	Reference Number	Action
27 September 2013	10143725	Addition of CTO indication for the MINI TREK RX and MINI TREK OTW. Addition of MINI TREK II OTW catalogue codes with the CTO indication.
10 April 2015	10154737	Certificate Renewal.
08 July 2015	10156506	Addition of Sterigenics Costa Rica S.R.L. for ETO sterilization.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.

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Page 7 of 7

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