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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2010-04-20** Date: **2020-06-29** Expiry Date: **2024-05-26**

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Supplementary Information to CE 561260

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MINI TREK RX Coronary Dilatation Catheters

Intended purpose per IFU:

The MINI TREK RX Coronary Dilatation Catheter is indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction
c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm only)
d) Balloon dilatation of *de novo* chronic total occlusions (CTO)

Classification: Class III

Catalog Numbers:

Balloon Diameter (mm)	Balloon Length						
	6mm	**8mm**	**12mm**	**15mm**	**20mm**	**25mm**	**30mm**
1.20	1012268-06	1012268-08	1012268-12	1012268-15	1012268-20	---	---
1.50	1012269-06	1012269-08	1012269-12	1012269-15	1012269-20	---	---
2.00	1012270-06	1012270-08	1012270-12	1012270-15	1012270-20	1012270-25	1012270-30

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TREK RX Coronary Dilatation Catheters							
Intended purpose per IFU:							
The TREK RX Coronary Dilatation Catheter is indicated for: a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction c) Balloon dilatation of a stent after implantation							
Classification: Class III							
Catalog Numbers:							
Balloon Diameter (mm)	**Balloon Length**						
	6mm	**8mm**	**12mm**	**15mm**	**20mm**	**25mm**	**30mm**
2.25	1012271-06	1012271-08	1012271-12	1012271-15	1012271-20	1012271-25	1012271-30
2.50	1012272-06	1012272-08	1012272-12	1012272-15	1012272-20	1012272-25	1012272-30
2.75	1012273-06	1012273-08	1012273-12	1012273-15	1012273-20	1012273-25	1012273-30
3.00	1012274-06	1012274-08	1012274-12	1012274-15	1012274-20	1012274-25	1012274-30
3.25	1012275-06	1012275-08	1012275-12	1012275-15	1012275-20	1012275-25	1012275-30
3.50	1012276-06	1012276-08	1012276-12	1012276-15	1012276-20	1012276-25	1012276-30
3.75	1012277-06	1012277-08	1012277-12	1012277-15	1012277-20	1012277-25	1012277-30
4.00	1012278-06	1012278-08	1012278-12	1012278-15	1012278-20	1012278-25	1012278-30
4.50	---	---	1012279-12	1012279-15	---	---	---
5.00	---	---	1012280-12	1012280-15	---	---	---

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MINI TREK OTW Coronary Dilatation Catheters							
Intended purpose per IFU:							
The MINI TREK OTW Coronary Dilatation Catheter is indicated for: a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm only)							
Classification: Class III							
Catalog Numbers:							
Balloon Diameter (mm)	**Balloon Length**						
	6mm	**8mm**	**12mm**	**15mm**	**20mm**	**25mm**	**30mm**
1.20	1012401-06	1012401-08	1012401-12	1012401-15	1012401-20	---	---
1.50	1012402-06	1012402-08	1012402-12	1012402-15	1012402-20	---	---
2.00	1012403-06	1012403-08	1012403-12	1012403-15	1012403-20	1012403-25	1012403-30

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TREK OTW Coronary Dilatation Catheters							
Intended purpose per IFU:							
The TREK OTW Coronary Dilatation Catheter is indicated for: a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction c) Balloon dilatation of a stent after implantation							
Classification: Class III							
Catalog Numbers:							
Balloon Diameter (mm)	**Balloon Length**						
	6mm	**8mm**	**12mm**	**15mm**	**20mm**	**25mm**	**30mm**
2.25	1012404-06	1012404-08	1012404-12	1012404-15	1012404-20	1012404-25	1012404-30
2.50	1012405-06	1012405-08	1012405-12	1012405-15	1012405-20	1012405-25	1012405-30
2.75	1012406-06	1012406-08	1012406-12	1012406-15	1012406-20	1012406-25	1012406-30
3.00	1012407-06	1012407-08	1012407-12	1012407-15	1012407-20	1012407-25	1012407-30
3.25	1012408-06	1012408-08	1012408-12	1012408-15	1012408-20	1012408-25	1012408-30
3.50	1012409-06	1012409-08	1012409-12	1012409-15	1012409-20	1012409-25	1012409-30
3.75	1012410-06	1012410-08	1012410-12	1012410-15	1012410-20	1012410-25	1012410-30
4.00	1012411-06	1012411-08	1012411-12	1012411-15	1012411-20	1012411-25	1012411-30
4.50	---	---	1012412-12	1012412-15	---	---	---
5.00	---	---	1012413-12	1012413-15	---	---	---

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MINI TREK II OTW Coronary Dilatation Catheters

Intended purpose per IFU:

The MINI TREK II OTW Coronary Dilatation Catheter is indicated for:
a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis, for the purpose of improving myocardial perfusion
b) Balloon dilatation of a coronary artery occlusion, for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction
c) Balloon dilatation of a stent after implantation (balloon models 2.00 mm only)
d) Balloon dilatation of *de novo* chronic total occlusions (CTO)

Classification: Class III

Catalog Numbers:

Balloon Diameter (mm)	Balloon Length						
	6mm	**8mm**	**12mm**	**15mm**	**20mm**	**25mm**	**30mm**
1.20	1012401-06A	1012401-08A	1012401-12A	1012401-15A	1012401-20A	---	---
1.50	1012402-06A	1012402-08A	1012402-12A	1012402-15A	1012402-20A	---	---
2.00	1012403-06A	1012403-08A	1012403-12A	1012403-15A	1012403-20A	---	---

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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.
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.

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Date	Reference Number	Action
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.
27 February 2019	7780598	Traceable to NB 0086.
07 April 2020	9757906	Certificate renewal. Reformatting of the supplementary information product table.
Current	8936174	IFU and labelling updates to Coronary Dilatation Catheters.

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