EC Design-Examination Certificate

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

No. **CE 565938**

Issued To: **Abbott Vascular**
3200 Lakeside Drive
Santa Clara
California
95054
USA

In respect of:

NC TREK RX Coronary Dilatation Catheter

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: **2010-09-08** Date: **2020-04-15** Expiry Date: **2024-05-26**

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NC TREK RX Coronary Dilatation Catheter

Intended purpose per IFU:

The NC 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 – 5.00 mm only)

Classification: Class III

Catalog Numbers:

Balloon Diameter (mm)	Balloon Length					
	6mm	8mm	12mm	15mm	20mm	25mm
1.50	1012444-06	1012444-08	1012444-12	1012444-15	1012444-20	---
2.00	1012445-06	1012445-08	1012445-12	1012445-15	1012445-20	---
2.25	1012446-06	1012446-08	1012446-12	1012446-15	1012446-20	---
2.50	1012447-06	1012447-08	1012447-12	1012447-15	1012447-20	1012447-25
2.75	1012448-06	1012448-08	1012448-12	1012448-15	1012448-20	---
3.00	1012449-06	1012449-08	1012449-12	1012449-15	1012449-20	1012449-25
3.25	1012450-06	1012450-08	1012450-12	1012450-15	1012450-20	---
3.50	1012451-06	1012451-08	1012451-12	1012451-15	1012451-20	1012451-25
3.75	---	1012452-08	1012452-12	1012452-15	1012452-20	---
4.00	---	1012453-08	1012453-12	1012453-15	1012453-20	---
4.50	---	1012454-08	1012454-12	1012454-15	1012454-20	---
5.00	---	1012455-08	1012455-12	1012455-15	1012455-20	---

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Certificate History

Date	Reference Number	Action
08 September 2010	10118774	First Issue – Rebranding of device from Voyager NC (CE 83267) and minor changes.
07 January 2011	10118950	Line extension for the NC TREK RX to add 12 new catalogue codes; Correction to add catalogue code 1012447-08 inadvertently omitted during the previous review under EQ 10118774. IFU updated to include "not to exceed 10 total inflations" on Instructions for Use section.
16 November 2012	10137567	Addition of Abbott Vascular manufacturing site in Alajuela, Costa Rica for NC TREK RX catalogue codes.
08 July 2015	10156506	Addition of Sterigenics Costa Rica S.R.L. for ETO sterilization.
28 August 2015	10158229	Certificate renewal.
12 January 2016	10159718	DuPont Tyvek Medical Transition Project update.
18 February 2019	9642892	Review of changes to in-process inspection instructions to address the protective sheath placement.

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Date	Reference Number	Action
27 February 2019	7780598	Traceable to NB 0086.
Current	9757908	Certificate renewal. Reformatting of the supplementary information product table.

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