By Royal Charter

# EC Design-Examination Certificate

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

**No.** **CE 503252**

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

In respect of:

**X.ACT Carotid Stent System**

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: **2006-01-19** Date: **2020-04-10** Expiry Date: **2024-05-26**

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| Catalogue Number | Device Name | Model, Type | | | Intended purpose per IFU | Classification |
|---|---|---|---|---|---|---|
| | | Configuration | Length (mm) | Diameter (mm) | | |
| XRX 020 07S | X.ACT Carotid Stent System | Straight | 20 | 7 | The X.ACT Carotid Stent System is indicated for use in patients with atherosclerotic disease of the carotid arteries.<br><br>The X.ACT Carotid Stent System is indicated for use in conjunction with Abbott Vascular's Accunet or Emboshield family of Embolic Protection Systems (EPS). | Class III - Implant |
| XRX 020 08S | | Straight | 20 | 8 | | |
| XRX 020 09S | | Straight | 20 | 9 | | |
| XRX 020 10S | | Straight | 20 | 10 | | |
| XRX 030 07S | | Straight | 30 | 7 | | |
| XRX 030 08S | | Straight | 30 | 8 | | |
| XRX 030 09S | | Straight | 30 | 9 | | |
| XRX 030 10S | | Straight | 30 | 10 | | |
| XRX 030 08T | | Tapered | 30 | 8-6* | | |
| XRX 030 09T | | Tapered | 30 | 9-7* | | |
| XRX 030 10T | | Tapered | 30 | 10-8* | | |
| XRX 040 08T | | Tapered | 40 | 8-6* | | |
| XRX 040 09T | | Tapered | 40 | 9-7* | | |
| XRX 040 10T | | Tapered | 40 | 10-8* | | |
| * Indicates Proximal to Distal Diameter | | | | | | |

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# Certificate History

| Date | Reference Number | Action |
|---|---|---|
| 19 January 2006 | 10075873 | Transfer from another Notified Body |
| 01 February 2007 | 10082913 | Changes to the handle components of the Xact Carotid Stent System delivery system |
| 26 February 2009 | 10103026 | Update the manufacturer's name and address, change the sterilization site to Sterigenics, CA, change the manufacturing location from Abbott Ireland Vascular Division in Galway Ireland to Abbott Vascular, Temecular, CA and review minor product changes. |
| 08 December 2010 | 10119194 | Certificate Renewal for five year period |
| 26 September 2012 | 10134045 | Indication Change to include standard risk patients. Branding change to replace "Xact" with "X.ACT". |
| 13 May 2015 | 10155215 | Introduction of electronic IFUs in compliance with Regulation 207/2012. |
| 29 October 2015 | 10158830 | Certificate Renewal for five year period |
| 12 January 2016 | 10159718 | DuPont Tyvek Medical Transition Project update. |
| 21 October 2016 | 10166067 | Addition of Sterigenics in Costa Rica as a significant subcontractor for ETO sterilization. |

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| Date | Reference Number | Action |
|---|---|---|
| 27 February 2019 | 7780598 | Traceable to NB 0086. |
| Current | 9753518 | Certificate renewal. Reformat product table and clarify tapered OD. |

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