By Royal Charter

# EC Design-Examination Certificate

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

**No.** **CE 707326**

Issued To: **Abbott Medical**
**5050 Nathan Lane North**
**Plymouth**
**Minnesota**
**55442**
**USA**

In respect of:

**Amplatzer™ Valvular Plug III**

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: **2020-01-20** Date: **2020-12-04** Expiry Date: **2024-05-26**

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**Supplementary Information to CE 707326**

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| Catalogue Number | Model, Type | Intended purpose per IFU | Classification |
|---|---|---|---|
| 9-APVL3-042 | 4 mm x 2 mm | The Amplatzer™ Valvular Plug III (AVPIII) is intended for percutaneous, transcatheter closure of a paravalvular leak that has developed after an aortic or mitral mechanical surgical valve implant procedure. The device is indicated for patients with a clinically significant paravalvular leak showing signs of heart failure and/or paravalvular leak-associated hemolysis, necessitating recurring blood transfusions. | Class III Implant |
| 9-APVL3-063 | 6 mm x 3 mm | | |
| 9-APVL3-084 | 8 mm x 4 mm | | |
| 9-APVL3-103 | 10 mm x 3 mm | | |
| 9-APVL3-105 | 10 mm x 5 mm | | |
| 9-APVL3-123 | 12 mm x 3 mm | | |
| 9-APVL3-125 | 12 mm x 5 mm | | |
| 9-APVL3-143 | 14 mm x 3 mm | | |
| 9-APVL3-145 | 14 mm x 5 mm | | |

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# Certificate History

| Date | Reference Number | Action |
|---|---|---|
| 20 January 2020 | 9722381 | First Issue. |
| Current | 3219644 | Addition of new ETO sterilization cycle ("soft cycle") and related chamber 12 at Isomedix Operations Inc. 380 90th Avenue NW Minneapolis, Minnesota 55433 USA.<br>Adoption of final-pack configuration (sterile-in-box) for ETO sterilization under "soft cycle" in chamber 12 at Isomedix Minneapolis, MN, US.<br>Re-design of shipper box for ETO sterilization under "soft cycle" in chamber 12 at Isomedix Minneapolis, MN, US.<br>Introduction of new 11-pallet load configuration for ETO sterilization under "soft cycle" in chamber 12 at Isomedix Minneapolis, MN, US.<br>Reformat of Amplatzer name in the certificate scope and product table. |

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