

# 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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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.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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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	<p>Addition of new ETO sterilization cycle ("soft cycle") and related chamber 12 at Isomedix Operations Inc. 380 90th Avenue NW Minneapolis, Minnesota 55433 USA.</p> <p>Adoption of final-pack configuration (sterile-in-box) for ETO sterilization under "soft cycle" in chamber 12 at Isomedix Minneapolis, MN, US.</p> <p>Re-design of shipper box for ETO sterilization under "soft cycle" in chamber 12 at Isomedix Minneapolis, MN, US.</p> <p>Introduction of new 11-pallet load configuration for ETO sterilization under "soft cycle" in chamber 12 at Isomedix Minneapolis, MN, US.</p> <p>Reformat of Amplatzer name in the certificate scope and product table.</p>

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