

Abbott Declaration of Conformity Amplatzer Valvular Plug III

Abbott Medical (Abbott) hereby declares that the following Abbott facilities and products conform to the applicable provisions of Annex II of the Medical Device Directive (MDD) 93/42/EEC. All supporting documentation is retained under the premises of Abbott. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address: Abbott Medical
5050 Nathan Lane North
Plymouth, Minnesota 55442, USA

European Representative: Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem, Belgium

Product Type: Cardiac Occluder

Product Name(s): Amplatzer Valvular Plug III

Model Number(s):

Product	Model Numbers	Original CE Mark Date
Amplatzer Valvular Plug III	9-APVL3-042 9-APVL3-063 9-APVL3-084 9-APVL3-103 9-APVL3-105 9-APVL3-123 9-APVL3-125 9-APVL3-143 9-APVL3-145	20 January 2020

Classification: Class III per Annex IX, Rule 8
GHTF Class D

GMDN Code(s): 45418

EC Design Certificate No and Expiration Date: Certificate No: CE 707326
Expiration Date: 26 May 2024

Signature:



Gabrielle Zaeska
Manager, Regulatory Affairs

4-15-21

Issue Date


**Abbott Declaration of Conformity
Amplatzer Valvular Plug III****Annex II, Clause 3 Certificate No and
Expiration date:**Certificate No: CE 694788
Expiration Date: 23 February 2023**Applicable Quality System Standards:**

ISO 13485

Notified Body:BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands**Notified Body Number:**

2797

Signature:

Gabrielle Zaeska
Manager, Regulatory Affairs

Issue Date