

22 March 2023

To Whom it May concern

We, Abbott Medical, located at 5050 Nathan Lane North, Plymouth, MN USA 55442, hereby confirm that the devices listed in Table 1 meet the following conditions as laid out in Regulation (EU) 2023/607 dated 20 March 2023:

- (a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
- (b) there are no significant changes in the design and intended purpose;
- (c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
- (d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);
- (e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

Sincerely,

Michelle Grossman
Sr. Director Regulatory Affairs

Table 1.

Device Name	MDD Certificate Numberⁱ	First issued	Expiry Dateⁱⁱ
Amplatzer™ Guidewires	CE 694955	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ LP Delivery System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ LP Catheter	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ Muscular VSD Occluder	CE 694951	03-Sep-18	23-Feb-23
Amplatzer™ P.I. Muscular VSD Occluder	CE 694951	03-Sep-18	23-Feb-23
Amplatzer™ Multifenestrated Septal Occluder-"Cribriform"	CE 694948	03-Sep-18	23-Feb-23
Amplatzer™ Duct Occluder	CE 694957	03-Sep-18	23-Feb-23
Amplatzer™ Duct Occluder II	CE 694957	03-Sep-18	23-Feb-23
Amplatzer Piccolo™ Occluder	CE 694957	03-Sep-18	23-Feb-23
Amplatzer™ Septal Occluder	CE 694948	03-Sep-18	23-Feb-23
Amplatzer Valvular Plug III	CE 707326	20-Jan-20	26-May-24
Amplatzer™ Amulet™ Delivery Sheath	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ 2 Delivery System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ TorqVue™ Delivery System Amplatzer™ TorqVue™ Exchange System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ Trevisio™ Intravascular Delivery System	CE 694956	03-Sep-18	23-Feb-23
Amplatzer™ Sizing Balloon II	CE 694959	03-Sep-18	23-Feb-23

ⁱ Number of certificate issued under Directive 90/385/EEC (MDD)

ⁱⁱ The expiry date on the certificate issued under Directive 90//385/EEC (MDD)