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14 Feb 2023

Our ref: CE 694948, CE 694951, CE 694955, CE 694956, CE 694957, CE 694959 (Expiry date: 23/Feb/2023); CE 707326 (Expiry date: 26/May/2024)

To whom it may concern,

Information to support the application of Article 97 of the Medical Device Regulation (EU 2017/745; MDR) to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate

This letter is issued pursuant to the principles laid out in MDCG 2022-18 to support the manufacturer's application for derogation under Article 97 of the MDR for the legacy devices (as described by MDCG 2021-5 and to which Article 120(3) of the MDR applies) identified below.

Legacy devices covered by this letter

This letter is limited to covering the following devices only:

Devices	**MDD Certificate, Annex II Section 4**		
	Certificate Number	**Certificate First issued**	**Certificate Expiry Date**
Amplatzer™ Multi-fenestrated Septal Occluder	CE 694948	2018-09-03	2023-02-23
Amplatzer™ Septal Occluder	CE 694948	2018-09-03	2023-02-23
Amplatzer™ Muscular VSD Occluder	CE 694951	2018-09-03	2023-02-23
Amplatzer™ Post-Infarct Muscular VSD Occluder	CE 694951	2018-09-03	2023-02-23

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Amplatzer™ Guidewires	CE 694955	2018-09-03	2023-02-23
Amplatzer™ TorqVue™ LP Delivery System	CE 694956	2018-09-03	2023-02-23
Amplatzer™ TorqVue™ LP Catheter	CE 694956	2018-09-03	2023-02-23
Amplatzer™ Amulet™ Delivery Sheath	CE 694956	2018-09-03	2023-02-23
Amplatzer™ TorqVue™ 2 Delivery Sheath	CE 694956	2018-09-03	2023-02-23
Amplatzer™ TorqVue™ Delivery System	CE 694956	2018-09-03	2023-02-23
Amplatzer™ TorqVue™ Exchange System	CE 694956	2018-09-03	2023-02-23
Amplatzer™ Trevisio™ Intravascular Delivery System	CE 694956	2018-09-03	2023-02-23
Amplatzer™ Duct Occluder	CE 694957	2018-09-03	2023-02-23
Amplatzer™ Duct Occluder II	CE 694957	2018-09-03	2023-02-23
Amplatzer™ Piccolo™ Occluder	CE 694957	2018-09-03	2023-02-23
Amplatzer™ Sizing Balloon II	CE 694959	2018-09-03	2023-02-23
Amplatzer™ Valvular Plug III	CE 707326	2020-01-20	2024-05-26

Confirmation

This letter confirms that:

- The certificate referred to above was issued by BSI under the requirements of the Medical Device Directive (93/42/EEC) (the "MDD");
- The certificate referred to covers the legacy device(s) specified above;
- The certificate referred to above is to expire shortly and remains valid at the date of this letter;
- An application under the MDR for the devices specified above has been accepted and the contract with the manufacturer signed;
- The estimated time to finalise the conformity assessment in accordance with the MDR for the subject device(s) is 12 months from the date of this letter. Please note that the estimated timescale by when conformity assessment under the MDR will be complete is subject to many factors, such as the quality of the manufacturer's technical documentation, manufacturer's responsiveness, Competent Authority's responsiveness and Notified Body resource with the correct competence codes.

Assumptions

BSI Group is issuing this letter on the following assumptions. BSI Group requires the manufacturer to inform it immediately if any of these assumptions are incorrect:

- the devices are not subject to any investigations by any regulatory authorities / notified bodies in relation to their safety;

- the manufacturer will provide the Competent Authority all the requisite information as per MDCG 2022-18, especially data concerning incidents and field safety corrective actions, to permit the Competent Authority to evaluate risk to the health and safety of patients;
- the Competent Authority will evaluate the risk associated with the devices to determine if there is no unacceptable risk to patient health or safety and thereby whether Article 97 may apply to the devices covered by the MDD certificate.

Conditions

This letter is issued subject to the following conditions:

- that the assumptions above remain correct at all times;
- that the manufacturer provides to the relevant Competent Authority any relevant information relating to the devices that demonstrate that the evaluation of the Competent Authority (that the devices do not present an unacceptable risk to patient health or safety) may need to be re-evaluated;
- that the manufacturer provides to BSI Group a copy of any authorisation granted by a Competent Authority under Article 97 of the MDR.

Providing these conditions are met, BSI Group will commit to providing the relevant Competent Authority information relating to any major safety-related shortcomings identified during conformity assessment under the MDR.

This confirmation letter remains valid for as long as the manufacturer continues to apply to meet the requirements of conformity assessment under the MDR, within the scope of a contract for such services it has with BSI Group.

Yours faithfully,

ChiaLei Ang
Scheme Manager