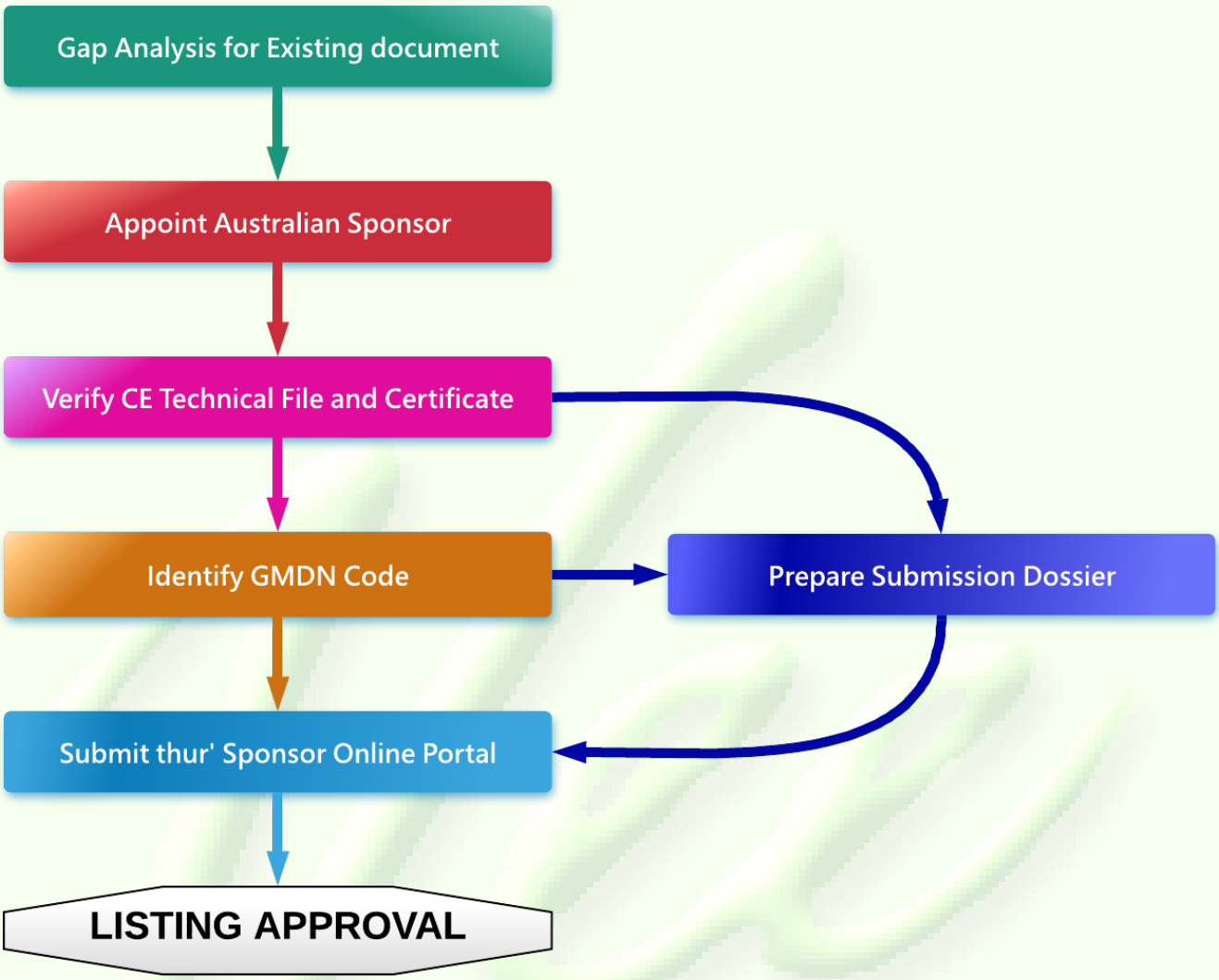
REGISTRATION PROCESS



MARKET ACCESS TO AUSTRALIA

DOCUMENTS REQUIRED

Administrative Information

- Manufacturers with a CE certificate must provide TGA with the following information:
- Copies of the current CE certificates hold by the manufacturer
- Copies of the Initial Certification audit report
- Copies of the current CE design Examination or Type Examination Certificate, if applicable
- Copies of the Design Examination or Type Examination reports issued by the Notified Body in support of the certificate, if applicable
- Evidence of close out of non-conformities

Technical Information

- A completed essential principles checklist
- Risk management report
- Clinical evidence
- Labeling
- Instructions for use
- Advertising material
- For class III devices and AIMDs the manufacturer shall also submit a Design Dossier. TGA may on review of this information conduct a reduced assessment of the quality system or may in some cases do an on-site audit [ARTG 34].