Application requirements for medical devices - preliminary assessment

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Applications for the inclusion of medical devices (including IVDs) in the ARTG must meet certain requirements in order to pass *preliminary assessment*. The requirements include providing conformity assessment documents that are appropriate for the category and Class of device.

To pass *preliminary assessment*, an application must meet the requirements in section 41FDB of the *Therapeutic Goods Act 1989 (https://www.legislation.gov.au/Series/C2004A03952)* (the Act). The TGA will carry out an assessment of whether the requirements have been met for each application. Applications that do not pass preliminary assessment will be refused by the TGA.

Specifically these requirements include that:

- The application must be made in accordance with the form and manner approved for the class of device (the application form in TGA Business Services (TBS) (https://business.tga.gov.au/) for the class of device).
- The application must be accompanied by certain information of a kind (and in a form) prescribed for the class of device in the **Use of market authorisation evidence from comparable overseas regulatory bodies for medical devices guidance document**.
- The applicant has certified the matters in section 41FD of the Act.
- The prescribed application fee for the class of medical device is paid.

An application that passes preliminary assessment will either proceed to the decision for the device to be included in the ARTG or application to be selected for audit.

The requirement to provide certain documentation with the application applies to all classes of medical device, except Class I (Export Only), Class 1 IVD and Class 1 IVD (Export Only).

This documentation is to accompany the device application as Manufacturer Evidence or as an attachment to the application form, as specified in the guidance document **Use of market authorisation evidence from comparable overseas regulatory bodies for medical devices** (htt

ps://www.tga.gov.au/node/285179).

Topics:

Medical devices (https://www.tga.gov.au/products/medical-devices)