About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.

- The TGA administers the Therapeutic Goods Act 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.

- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.

- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.

- To report a problem with a medicine or medical device, please see the information on the TGA website <http://www.tga.gov.au>.
## Version history

<table>
<thead>
<tr>
<th>Version</th>
<th>Description of change</th>
<th>Author</th>
<th>Effective date</th>
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<tbody>
<tr>
<td>V1.0</td>
<td>Most recent version prior to inclusion of Change History section.</td>
<td>Office of Devices Authorisation</td>
<td>15/11/2010</td>
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<tr>
<td>V1.1</td>
<td>Addition of Change History section. Clarification in section Formatting Instructions for Supporting Data on page 7 for applications with supporting data of 50 pages or less: Supporting documentation must now be sent as a single document (e.g., in PDF format). Update of section Fit-and-Proper Person Certification with new name Considering Applications Under Section 41EC (Fit-and-Proper Person) and information pursuant to changes to the Act that came into effect on 1 December 2009.</td>
<td>Office of Devices Authorisation</td>
<td>01/12/2010</td>
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<tr>
<td>V1.2</td>
<td>Reformatted for compliance with new TGA style manual Added Manufacturer Root File Number to Reference: TGA Identifiers table Added new sub-section: Applications for extension of time to submit responses to s41JA requests</td>
<td>Office of Devices Authorisation</td>
<td>12/05/2011</td>
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<tr>
<td>Version</td>
<td>Description of change</td>
<td>Author</td>
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<tr>
<td>V1.3</td>
<td>Updated section <em>Formatting Instructions for Supporting Data</em> to state that all supporting data and documents must be provided in a readable electronic format. Updated references to the term <em>audit</em> and its derivatives to <em>inspect</em> and its derivatives. Multiple minor grammatical alterations. Addition of link to TGA guideline for medical device assessment fee reduction.</td>
<td>Office of Devices Authorisation</td>
<td>07/11/2012</td>
</tr>
<tr>
<td>V1.4</td>
<td>Updated Department logo, copyright information, change of Branch name. Multiple minor text edits for clarity. Update of links and eBS information. Change of ACMD process to reflect current practice. Change of recertification submission timeframe.</td>
<td>Devices Authorisation Branch</td>
<td>27/04/2015</td>
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These instructions should be read in conjunction with Section 6. *What a manufacturer needs to know about conformity assessment* in the Australian Regulatory Guidelines for Medical Devices (ARGMD), which is available on the TGA website <http://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd>. 
Reference: TGA identifiers

The TGA uses a number of identifiers to track various elements of the conformity assessment application process. The identifiers used throughout this document are provided in the table below:

Reference table of identifiers

A list of the different record and number systems used during a conformity assessment application

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Format and example</th>
<th>Description and use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submission ID</td>
<td>Format: DC-YYYY-xxxxx-7 Example: DC-2009-54321-7</td>
<td>The primary ID used by the TGA to identify the application during the assessment process. Should be included on all correspondence with the TGA. Sometimes referred to as the ‘DC’ number. Is generated after the application fees are paid.</td>
</tr>
<tr>
<td>Application Identifier</td>
<td>Format: DV-YYYY-CA-xxxxxx-3 Example: DV-2009-CA-54321-3</td>
<td>Used to identify the electronic application. Is rarely referred to during a conformity assessment certification application. Is generated when a draft application is first saved.</td>
</tr>
<tr>
<td>Record Number or File Number</td>
<td>Format: YYYY/xxxxxx Example: 2009/001234</td>
<td>The identifier is used by the TGA to track the file(s) associated with an application or manufacturer. All correspondence with a manufacturer and all TGA reports are placed on the file (or series of files) or associated data container.</td>
</tr>
<tr>
<td>Certificate Number</td>
<td>Format: – AU Qxxxxx – AU Dxxxxx Examples: – AU Q00123 – AU D00123</td>
<td>The identifier used by the TGA to identify a manufacturer’s certificate(s). ・ AU Q is for an Australian Conformity Assessment quality system certificate ・ AU D is for an Australian Conformity Assessment design examination certificate ・ MRA Q is for an MRA (CE) Conformity Assessment quality system certificate ・ MRA D is for an MRA (CE) Conformity Assessment design examination certificate</td>
</tr>
<tr>
<td>Manufacturer Root File Number</td>
<td>Format: YYYY/xxxxxx Example: 2010/001234</td>
<td>The identifier for the file used by the TGA to store the manufacturer’s certificates.</td>
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</tbody>
</table>
How to apply

A diagram of the application process is provided at the end of this document.

Application steps

**Step 1 Create an e-Business account**

Before making an application, the manufacturer or an authorised person acting on behalf of the manufacturer must hold a client account with the TGA. With an e-Business (eBS) account, applicants can make applications for inclusion of medical devices on the Australian Register of Therapeutic Goods (ARTG) and applications for TGA Conformity Assessment Certification.

The eBS account provides industry with an integrated point of entry to TGA Online Services. The primary objective of TGA eBusiness Services (eBS) is to provide clients with the capability of viewing and managing their entire web based application activity with the TGA from a single, user portal.

TGA eBusiness Services (eBS) amalgamates draft applications into the ‘filterable' portal view and facilitates their final submission to the TGA.

eBS provides easy access for sponsors seeking information about their current entries on the ARTG (Australian Register of Therapeutic Goods) and TGA approved terminology, and it incorporates a facility that allows them to download and print their current ARTG certificates.

eBS enables users to effortlessly oversee all of their therapeutic product draft applications and apply for an amendment to, or cancellation of, their current ARTG records, online.


Step 2 Lodge an electronic application

Once the manufacturer or its representative has gained access to the eBS system, they may lodge an electronic application for a Conformity Assessment Certificate (or change or recertification application).

Click on Secure Login and log in to enter the system.

Click on Portal - Company name (User name) (1), then on Create Applications & Submissions (2), then on Medical Device (3), and then on Conformity Assessment (4) to open the application form.
Electronic attachments should not be included when completing the conformity assessment application form. Supporting information is to be submitted separately to the TGA (see below) only on request.

Upon submission of the application form, an application fee is payable to the TGA. Payment is made through a Payment Details Form included in the electronic application. (Failure to pay the application fee will result in the application being ineffective and consequently it will automatically lapse.)

Applicable assessment and onsite inspection fees are set at a later stage and are invoiced separately.

**Change applications**

When making change applications, the conformity assessment eBS form is used and the application fee is payable. The applicant should write ’Change to [aspect] for certificate(s): [Certificate numbers]’ in the Applicant’s Reference field of the eBS form. For example:

Should certificates be reissued by the delegate, device sponsors may need to submit the new certificate(s) as Manufacturer’s Evidence (possibly as a variation to Manufacturer’s Evidence). Depending on the change, sponsors may also need to make a new ARTG device inclusion application(s).

The actual application fee is displayed under ‘Application Type Details’ (Note: for current fees please consult the TGA website or Schedule 5 of the *Therapeutic Goods (Medical Devices) Regulations 2002*).
Recertification applications

When making recertification applications, the conformity assessment eBS form is used and the application fee is payable. The applicant should write ‘Recertification for certificate(s): [Certificate numbers separated by commas]’ in the Applicant’s Reference field of the eBS form. For example:

Should certificates be reissued by the delegate, device sponsors may need to submit the new certificate(s) as the manufacturer’s evidence (possibly as a variation to the manufacturer’s evidence). Depending on the change, sponsors may also need to make a new ARTG device inclusion application(s).

The actual application fee is displayed under ‘Application Type Details’ (Note: for current fees please consult the TGA website or Schedule 5 of the Therapeutic Goods (Medical Devices) Regulations 2002).

Step 3 Submit supporting documentation when requested

The applicant is usually required to submit additional information and data in support of the application. Once the electronic application is submitted and the application fee is processed, the application will be assigned a Submission ID (format DC-YYYY-xxxx-7, e.g., DC-2009-54321-7). All documents and correspondence regarding the application should reference the assigned Submission ID.

The TGA will send the applicant an email requesting further information and may require the applicant to complete a form called the Supporting Data Form—Conformity Assessment Certification and to provide supporting data. The form and associated data should only be provided when requested.

If you are a manufacturer applying for a Conformity Assessment Certificate, you should have in place a quality management system and technical documentation that complies with the requirements of the Therapeutic Goods (Medical Devices) Regulations 2002 (The Regulations). If this is not the case you may need to reapply at a later stage.
Formatting instructions for supporting data

Information and data should be organised for ease of reference (e.g., in a folder hierarchy, bookmarks in PDF document), and a table of contents provided. A cover letter that details all correspondence held with the TGA regarding the application should also be provided.

All supporting data and documents must be provided in a readable electronic format:

- Data and documents should be provided in PDF format as individual files (i.e. not joined together in a single PDF file). Other common file types (such as RTF or MS Word) may be accepted if PDF format is unavailable.
- The data provided must be searchable (either by generating the documents electronically and converting to PDF format, or by scanning in documents using optical character recognition (OCR)).
- Initial supporting data should be provided on CD-ROM or DVD-ROM media (preferably non-rewritable CD-R or DVD-R).
- Due to archiving and storage requirements, data submitted on USB storage media (or other electronic media such as hard-drives) may not be accepted.

As an option, a hardcopy of the supporting data package may also be submitted at the same time and in addition to the electronic data; however, this is not recommended.

The TGA will accept submissions in the IMDRF Non-In Vitro Diagnostic Device Market Authorization Table of Contents and the In Vitro Diagnostic Medical Device Market Authorization Table of Contents format provided that the document contains the requested information. For further information, please refer to the IMDRF website at <http://www.imdrf.org/documents/documents.asp>.

Where to deliver the supporting electronic documentation

When requested to provide documentation, please forward your response to:

<table>
<thead>
<tr>
<th>Postal address</th>
<th>Courier delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Devices Conformity Assessment Section</td>
<td>or</td>
</tr>
<tr>
<td>Medical Devices Branch</td>
<td>Devices Conformity Assessment Section</td>
</tr>
<tr>
<td>Therapeutic Goods Administration</td>
<td>Medical Devices Branch</td>
</tr>
<tr>
<td>PO Box 100</td>
<td>Therapeutic Goods Administration</td>
</tr>
<tr>
<td>WODEN ACT 2606</td>
<td>136 Narrabundah Lane</td>
</tr>
<tr>
<td></td>
<td>SYMONSTON ACT 2609</td>
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</table>

If you have any questions, please call the Medical Devices Information Line on 1800 141 144.

Fees and payments

Time frames

The TGA endeavours to meet industry-agreed time frames for assessments for conformity assessment certification. All time frames are given in *TGA working days* and start from the date the e-Business application fee is received. A working day is any day other than a weekend, a public holiday in the Australian Capital Territory, or when the TGA is waiting on information requested or waiting for payment of fees.

The agreed target time frames are:

• 90 working days for quality management system (QMS) certificates (for example, Part 1, Part 4 or Part 5 only)
  – + 60 working days if ACMD advice required

• 120 working days for Design or Type Examination certificates (for example, Clause 1.6 or Part 2)
  – + 60 working days if ACMD advice required

Applicants can enable efficient processing of applications by the TGA by ensuring that the documentation is of good quality, the application is well-structured, that there are no omissions in the submission, and that fees are paid promptly.

These are target times only and are not legislated. While the TGA will attempt to meet target times, it may not always be possible (e.g. when onsite inspections are required as part of a QMS certificate application assessment).
What happens next?

Pre-assessment

Once the application and supporting documentation are received by the TGA, the Devices Conformity Assessment Section will commence a pre-assessment of the application. If the TGA finds that in general the applicant has not provided sufficient information as will allow the certificate to be issued, the application may lapse.

Further information for clarification purposes may be necessary at the pre-assessment stage, or later in the application assessment. The TGA may send a request for information to the applicant under section 41JA of the Act. Failure to provide the required information and/or data within the time specified in the request will result in the application automatically lapsing. If the application lapses, the applicant will need to make a new application.

Applications for extension of time to submit responses to s41JA requests

Extensions for applicants to respond to s41JA requests may be granted only in extenuating circumstances. Such circumstances could include, but are not limited to, the following:

- manufacturer severely affected by a natural disaster (e.g., severe flood, earthquake, fire)
- death or serious illness of key personnel within the manufacturer's facility(ies) normally responsible for obtaining such information
- manufacturer's premises recently destroyed by fire or damage/loss as a result of theft or break-in

Situations that would not be considered to be extenuating include:

- the manufacturer being away on holidays
- the applicant only checking their mail recently or not realising that the TGA had requested the information
- the manufacturer needing time to have the information translated
- the manufacturer needing extra time to generate the documents or conduct testing

Applicants must make requests for extensions of time as early as possible (and before the due date), and should include detailed reasons for requesting the extension, as well as a suggested time frame for a response. Extensions of time may be made to the delegate requesting the information.

Application acceptance

Should the submission be found complete and acceptable for assessment the applicant will be sent an acceptance letter, and the associated assessment fees will be invoiced.

On-site inspection

If an on-site inspection of the manufacturer is required, this will be scheduled by a TGA Manufacturing Quality Branch (MQB) officer/inspector. An inspector from MQB will contact the manufacturer to arrange a suitable inspection time. Some on-site inspection fees (e.g. travel) are invoiced separately from the application assessment fees.
Advisory Committee on Medical Devices

Some conformity assessment applications for high risk devices, or devices with novel technology, may involve consultation with the Advisory Committee on Medical Devices (ACMD). The ACMD is a panel of academic and clinical specialist experts and also includes a consumer representative. In these cases, TGA assessors pose specific questions that are relevant to the assessment of the application, to the committee. If the TGA does decide to seek advice from the ACMD, the applicant will be advised prior to the meeting. Following the meeting, the applicant will be provided the questions posed to the ACMD and the responses provided by the committee.

Considering applications under section 41EC (fit-and-proper person)

On 1 December 2009, a series of amendments made in June 2009 to the Therapeutic Goods Act 1989 (the Act) took effect. This included changes to the requirements for fit-and-proper persons in relation to manufacturing licences and for Conformity Assessment Certificates (Sections 38(1)(g)-(h) and 41(1)(a) of the Act refer).

In order to administer this new legislation, the TGA has developed forms covering situations where particular information needs to be disclosed to the TGA.

For further information, please refer to the TGA website: <https://www.tga.gov.au/form/manufacturer-statutory-declarations>.

To reduce processing times, please send the completed Certificate by email to gmp@tga.gov.au. Please ensure that your email identifies the number of the associated Conformity Assessment Certificate.

If email delivery is not an available option, then the completed Certification may be submitted by fax to 02 6232 8426, or by post to the following address:

The Licensing and Certification Section
Manufacturing Quality Branch
PO Box 100
Therapeutic Goods Administration
WODEN ACT 2606

Issuing of certificates

Certificates will only be issued to the manufacturer once the following conditions are met:

• the assessment of the device’s compliance to the essential principles is completed and demonstrated by the manufacturer;

• the quality system inspection (if conducted) is closed out—that is, all non-conformities are resolved;

• all contractual arrangements for CE Marking (if applicable) are completed;

• all clearances (including the fit-and-proper person certification, if applicable) are completed; and

• all fees (application, assessment, additional inspection fees, etc.) are paid in full.

Certificates are issued to the manufacturer by the Devices Conformity Assessment Section of the Medical Devices Branch. Sponsors may use the certificates as evidence to support ARTG inclusions in order to supply the device(s) to the Australian market.
Legal supply in Australia (inclusion on the ARTG)

Once a certificate is issued to a manufacturer, device sponsors may:

1. lodge the certificate to be registered as Manufacturer’s Evidence (ME); and
2. apply for the inclusion of the device(s) on the ARTG using the ME to support the application(s).

A device cannot be legally supplied in Australia unless the sponsor holds a current ARTG entry for the device. (Instructions for submitting the Manufacturer’s Evidence and for making device inclusion applications are provided to applicants when the certificates are issued.)

Applications for Manufacturer’s Evidence take up to 15 TGA working days to process.

Applications for inclusion of medical devices on the ARTG may be made upon acceptance of the Manufacturer’s Evidence and can take up to 5 TGA working days to process when TGA certificates are used as Manufacturer’s Evidence.

Manufacturer’s Evidence for TGA Conformity Assessment Certificates are processed by the Devices Conformity Assessment Section while applications for inclusion of the device(s) in the ARTG are processed by the Devices Application and Verification Section.
Substantial changes

You must inform the TGA of any plans for substantial changes to the quality system or range of products as defined in the certificates, prior to making the change. Applications for substantial change can be made using the e-Business system. Please note that, at a minimum, changes to any of the following constitute a substantial change:

- any detail on the certificate including manufacturer’s name or address
- changes to GMDN codes for IVD devices only, and for both IVD and non-IVD devices, changes to product scope, or to unique product identifiers
- additions or deletions of new critical suppliers
- substantial changes to critical processes (e.g., change of sterilisation method)
- facility name or address
- changes to the design of the device that may affect its compliance with the essential principles
- change of source for materials of animal origin

When making change applications, the standard conformity assessment eBS form is used. The applicant should write ‘Change to [aspect] for certificate(s): [Certificate numbers]’ in the description field of the eBS form.

Once certificates are reissued, device sponsors may need to apply to have the certificates re-registered as Manufacturers’ Evidence (possibly as a variation). Depending on the change, sponsors may also need to make new device inclusion application(s).

Recertification

Applications for recertification should be made at least six months prior to expiry of the manufacturer’s certificate(s). When making recertification applications, the standard conformity assessment eBS form is used. The applicant should write ‘Recertification for certificate(s): [Certificate numbers separated by commas]’ in the description field of the eBS form.

The TGA endeavours to remind applicants about upcoming certificate expiries in time for recertification applications to be processed, but it remains the responsibility of the manufacturer to ensure that recertification applications are made in sufficient time for the application to be completed and new certificates issued.

Once new certificates are issued, device sponsors may need to apply to have the certificates re-registered as Manufacturer’s Evidence (possibly as a variation). Depending on the change, sponsors may also need to make new device inclusion application(s).
Further information

Applicants are encouraged to reference the Australian Regulatory Guidelines for Medical Devices (ARGMD), which are available on the TGA website <https://www.tga.gov.au>.

Additional information may also be found on the medical devices page on the TGA website.

Medical Devices Information Line, Medical Devices Branch:

- Phone: 1 800 141 144.
- Email: devices@tga.gov.au

Providing feedback

Please send comments or suggestions for improvement about these instructions to:

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<thead>
<tr>
<th>Postal address</th>
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<tbody>
<tr>
<td>Devices Conformity Assessment Section Medical Devices Branch Therapeutic Goods Administration PO Box 100 WODEN ACT 2606</td>
<td>or Devices Conformity Assessment Section Medical Devices Branch Therapeutic Goods Administration 136 Narrabundah Lane SYMONSTON ACT 2609</td>
</tr>
</tbody>
</table>
**Application process flowchart**
Flowchart describing the conformity assessment certification application process

1. Applicant submits conformity assessment application through eBS and pays application fee
2. TGA writes to Applicant providing Submission ID and requesting supporting documentation
3. Applicant provides requested supporting information
4. If requirements are met, TGA issues TGA Conformity Assessment Certificate(s)
5. Applicant submits conformity assessment application through eBS and pays application fee
6. ACMD consulted for higher risk products (if required)
7. TGA conducts assessment, including an onsite inspection, if required
8. Applicant pays assessment fees
9. If information is satisfactory, TGA determines assessment needed and invoices assessment fees
10. Ongoing TGA surveillance activities/inspections
11. Recertification prior to expiry of certificate
12. For supply of device in Australia, Sponsor applies for device inclusion(s) using Conformity Assessment Certificate as evidence.

**TGA target time frames from the date eBusiness application submitted**
- 90 TGA working days
- if Design or Type examination required under Clause 1.6 then 120 TGA working days
- if ACMD advice required then an additional 60 TGA working days

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1. An applicant may be a manufacturer or their agent or representative
2. Advisory Committee for Medical Devices
3. A sponsor may be a manufacturer or their agent or representative. Multiple sponsors may reference the same certification as evidence.