Australian Government
Department of Health
Therapeutic Goods Administration

Application instructions

TGA Conformity assessment certification

Version 1.5, December 2020

TGA Health Safety Regulation

Contents

These instructions should be read in conjunction with the Australian Regulatory Guidelines for Medical Devices (ARGMD), which is available on the TGA website, select **Conformity Assessment**.

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

Identifier	Format and example	Description and use
Submission ID	Format: DC-YYYY-xxxx-1 Example: DC-2022-54321-1	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
Application Identifier	Format: DV-YYYY-CA-xxxxx-1 Example: DV-2022-CA-54321-1	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
Record Number or File Number	Format: YYYY/xxxxxx Example: 2022/001234	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.

Identifier	Format and example	Description and use
Certificate Number	Format: – AU Qxxxxx – AU Dxxxxx Examples: – AU Q00123 – AU D00123 Format: – MRA Qxxxxx Examples: – MRA Q00123	The identifier used by the TGA to identify a manufacturer's certificate(s). • *AU Q* is for an Australian Conformity Assessment quality management system certificate • *AU D* is for an Australian Conformity Assessment design examination certificate • *MRA Q* is for an MRA (CE) Conformity Assessment quality management system certificate
Version Number	Format: R.C Example: 2.1	The identifier used by the TGA to identify the version of the certificate • R represents the number of recertifications undertaken for the certificate • C represents the number of changes that have occurred since the most recent recertification
Manufacturer Root File Number	Format: YYYY/xxxxxx Example: 2021/001234	The identifier for the file used within the TGA to store the manufacturer's certificates.

How to apply: Application steps

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

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 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 managing and following up their entire web based application activity with the TGA from a single, user portal.

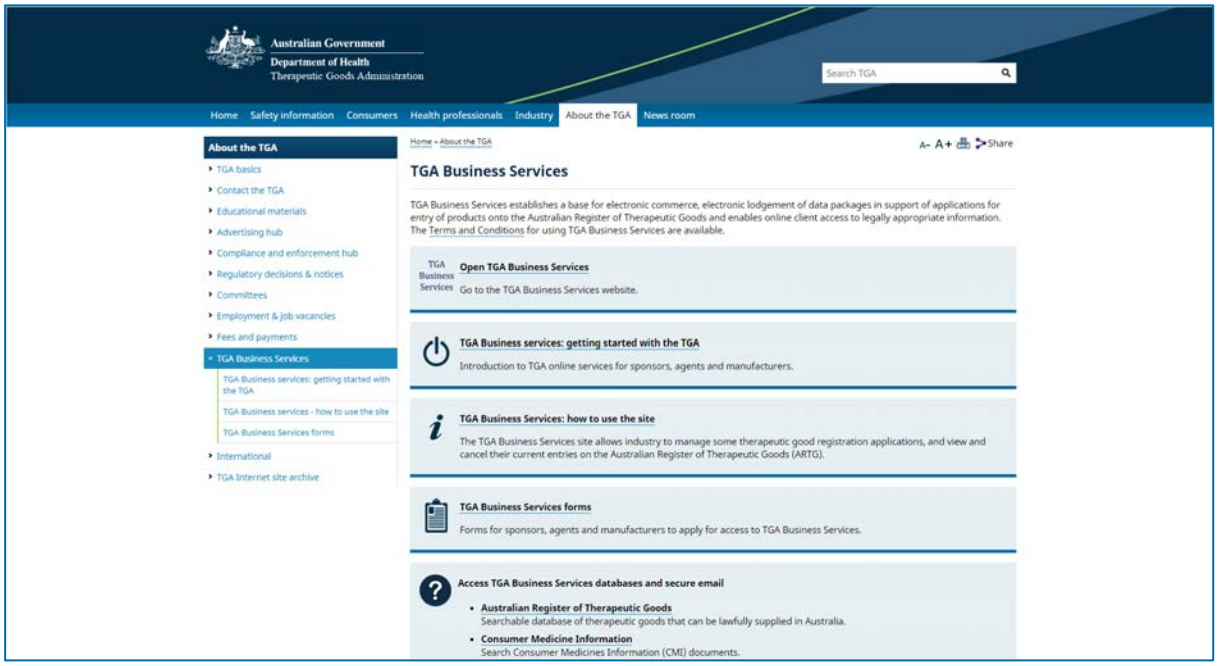
TGA eBusiness Services (eBS) amalgamates draft applications into the 'filterable' portal view and facilitates their final submission to the TGA.

Information on applying for a client identification number and access to eBS is available at TGA business services: getting started with the TGA which is available on the TGA website.

The e-Business forms are at TGA business-services-forms on the TGA website.

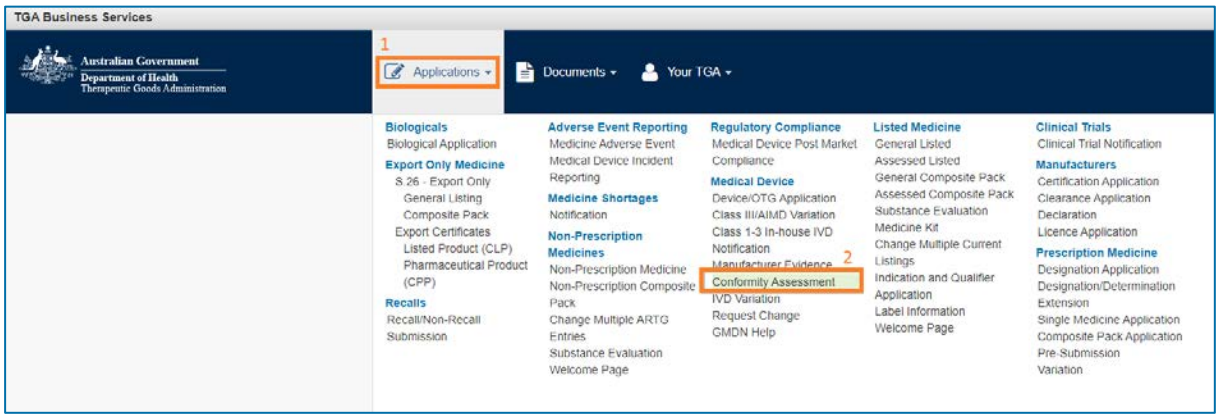
Step 2 – Lodge an electronic application through the TGA Business Services Portal

Applications for conformity assessment can be submitted through the TGA Business Services Portal at TGA Business Services which is available on the TGA website, **select Open TGA Business Services** and login to enter the system.



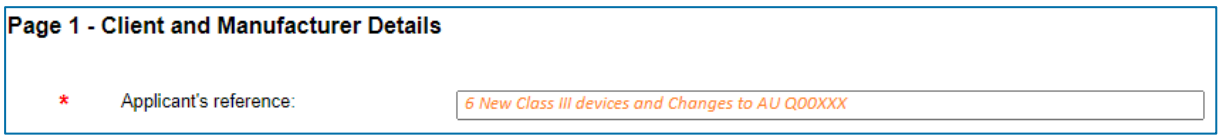
Once the manufacturer or its representative has gained access to the eBS system, they may lodge an electronic application for a Conformity Assessment Certificate (initial application, substantial change notification and application or recertification of an expiring certificate).

Click on **Applications (1)** then select **Medical Devices: Conformity Assessment (2)** and complete the application form.



Applicant's reference for initial applications

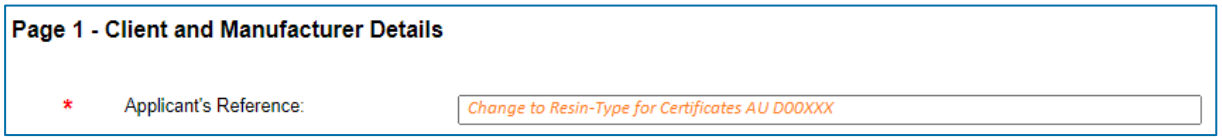
When making an initial application for a new certificate (for example, for an initial assessment of the manufacturer's quality management system or for a new kind of device), the applicant should include a description of the new entity / device in the applicant's reference field. If possible, also indicate if a subsequent change to an associated certificate is required. For example:



Electronic attachments should not be included when submitting the electronic application form for a Conformity Assessment Certificate. Supporting information is submitted separately to the TGA (see below) only on request.

Applicant's reference for substantial change notification and application

When making a substantial change notification and application the applicant should write '*Change to [aspect] for certificate(s): [Certificate numbers]*' in the Applicant's Reference field. For example:



Applicant's reference for recertification applications

When making an application for recertification of an expiring certificate, the applicant should write "*Recertification for certificate(s): [Certificate IDs separated by commas]*" in the applicant's reference field. For example:

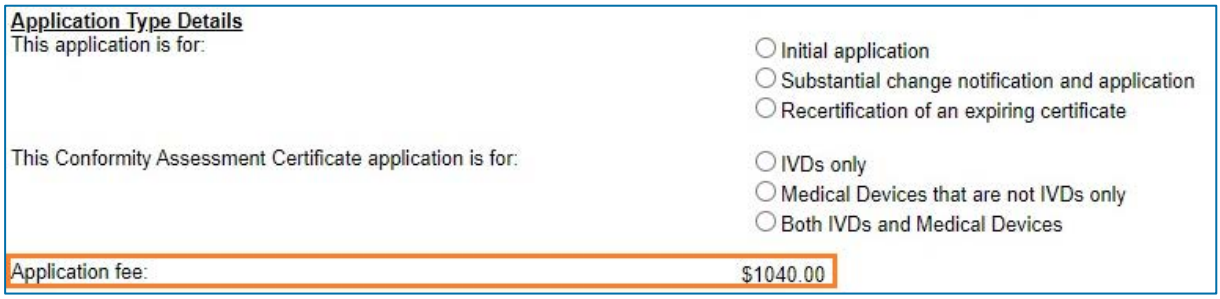
Step 3 - Payment of the application fee

Upon submission of the electronic application form, an application fee is payable to the TGA. Payment is made through the online invoice payment portal included in the eBS portal.

Please note that failure to pay the application fee will result in the application being ineffective and consequently it will automatically lapse.

The application fee is displayed under 'Application Type Details'.

(Note: for current fees please refer to the TGA website or Schedule 5 of the *Therapeutic Goods (Medical Devices) Regulations 2002*).



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

Step 4 - Submit supporting documentation when requested

Once the electronic application is submitted and the application fee is paid, the application will be assigned a **Submission ID** (format DC-YYYY-xxxx-1). All documents and correspondence regarding the application should reference the assigned Submission ID.

The TGA will send the applicant an acknowledgement email and request for supporting information. This request may require the applicant to complete a form "*Supporting Data Form—Conformity Assessment Certification*" and to provide supporting data. The form and associated data should **only** be provided when requested.

The form is available under **forms** at Application for conformity assessment certificates (medical devices).

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 should apply at a later stage when they are ready. Submission of insufficient supporting data may lead to applications being lapsed.

Formatting instructions for supporting data

Information and data should be organised for ease of reference (for example, in a folder hierarchy, bookmarks in PDF document), and a table of contents provided.

Cover letter

A cover letter that details all correspondence held with the TGA regarding the application should also be provided.

Include in the cover letter any relevant information that cannot be included in the supporting data form.

If there are similarities between the device you are applying for and the predicate device, produced by the same manufacturer that is supported by TGA conformity assessment certificate, you are advised (in tabular format within in the cover letter) to clearly highlight the similarities and differences between the new device and the predicate device with respect to their design, construction, materials (including formulation), intended purpose, administration, packaging materials, sterilisation process and shelf-life.

Supporting documents

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 a CD or DVD (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.

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 IMDRF Documents / IMDRF technical Documents.

Where to deliver the supporting electronic documentation

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

Postal address		Courier delivery
Devices Conformity Assessment Section Medical Devices Branch Therapeutic Goods Administration PO Box 100 WODEN ACT 2606	or	Devices Conformity Assessment Section Medical Devices Branch Therapeutic Goods Administration 136 Narrabundah Lane SYMONSTON ACT 2609

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

What happens next?

Once the application and supporting documentation has been received by the TGA, the Devices Conformity Assessment Section will commence a pre-assessment. This is a preliminary screening of the provided supporting documentation. If the TGA finds that in general the applicant has not provided sufficient information to allow commencement of assessment, the application may lapse.

Further information for clarification purposes may be necessary at the pre-assessment stage. The TGA may send a request for information to the applicant under section 41JA of the *Therapeutic Goods Act 1989* (the Act). When the request for information under section 41JA of the Act is sent to the applicant, the assessment clock for the application is stopped. The assessment clock restarts when all responses to the request for information is received by the TGA.

Failure to provide the required information and/or data within the time specified in the request for information will result in the application automatically lapsing. If the application lapses, the applicant will need to make a new application.

The pre-assessment results in the creation of an Assessment Plan and a determination of the associated assessment fees required to undertake assessment for the relevant application.

Applications for extension of time to submit responses to section 41JA 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 timeframe for a response. Extensions of time may be made to the delegate requesting the information. Applicants should be aware that each request for extension is considered case by case. In the case where an extension has been granted, this should not be considered as a precedent for such requests in the future.

Acceptance and assessment fees and payment

Should the submission be found complete and acceptable for assessment to commence (determined during pre-assessment), the applicant will be sent a fees notification email and the associated assessment fees will be invoiced.

Details of fees, payments and a copy of the TGA guideline for reduction of medical device assessment fees may be found on the TGA website at Fees and Payments and Reduction of assessment fees for medical devices.

Assessment

Following receipt of the assessment fees, the supporting data are sent to the relevant technical teams for assessment.

Further information for clarification purposes may be necessary during the assessment stage. The TGA may send a request for information to the applicant under section 41JA of the *Therapeutic Goods Act 1989* (the Act). Failure to provide the required information and/or data within the time specified in the request for information will result in the application automatically lapsing. If the application lapses, the applicant will need to make a new application.

Quality management system audits

If an audit of the manufacturer is required, this will be scheduled by the Devices Quality Audits and Assessments Section (DQAAS) of the TGA. An officer from DQAAS will contact the manufacturer to arrange a suitable audit time. Additional audit fees such as any travel-associated expenses for the audit and any audit time in excess of two audit days will be invoiced separately.

Type examination

If the application is for Type Examination certificate requiring testing, analysis, and reporting on examination of the type as described in Schedule 3, Part 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*, an additional fee to cover the costs associated with testing the relevant kind of medical device is also payable. The fee is the amount that reimburses the Department for the costs incurred in purchasing, establishing and setting-up the equipment to be used to conduct the tests and the direct costs of conducting the tests (including the cost of any consumables used in conducting the tests).

Supplementary assessment

If the application is for a medical device that requires supplementary assessment (for example for devices containing a medicinal substance) additional assessment fees prescribed in Item 1.12 of Schedule 5 of the *Therapeutic Goods (Medical Devices) Regulations 2002* may be applicable. If the medicinal substance contained in the medical device is a new chemical entity, additional fees prescribed under Item 4, or paragraph (b) or (d) of Item 5, of Part 2 of Schedule 9 to the *Therapeutic Goods Regulations 1990* may be applicable for assessment of the data relating to this medicinal substance.

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 fee for electronic application for a Conformity Assessment Certificate 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 (Clause 1.6) or Type Examination certificates
  - + 60 working days if ACMD advice required

These are target times only and are not legislated. Whilst the TGA will attempt to meet target times, this may not always be possible (for example, when onsite audits are required as part of the application assessment).

Applicants can enable efficient processing of applications by the TGA by ensuring that the documentation is of good quality, is well-structured, there are no omissions in the submission, the responses to any request for information are complete and that fees are paid promptly.

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.

Applicant's Statutory Declaration under section 41EC of the Act

In deciding whether to issue a Conformity Assessment Certificate under section 41EC of the Act the Secretary, or delegate, must, under paragraph 41EC(3)(a) of the Act, consider whether an applicant for a Conformity Assessment Certificate, or specified persons associated with an application for a Conformity Assessment Certificate, has, during the period of 10 years immediately before the application, failed to meet one or more of a number of specified criteria, including whether any of the relevant persons have been convicted of an offence against the Act or a corresponding State law.

In deciding whether to issue a Conformity Assessment Certificate, the Secretary, or delegate, must consider the matters set out under paragraph 41EC(3)(a) of the Act. For further information, please refer to Manufacturer Statutory Declarations.

The applicant's declaration is requested as part of the initial supporting data. To complete the form go to Manufacturer Statutory Declarations and select certificate S41EC(3)(a).

To reduce processing times, please send the completed applicant's declaration by email to dcas@health.gov.au. Please ensure that your email identifies the submission identification number (i.e. Submission ID) of the associated Conformity Assessment Application.

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 management system audit (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 certificate under section 41EC, if applicable) are completed; and
- all fees (application, assessment, additional audit fees, etc.) are paid in full.

Certificates are issued to the manufacturer by the Devices Conformity Assessment Section of the Medical Devices Authorisation Branch (MDAB). Sponsors can use the certificate(s) as evidence to support inclusion of the medical device(s) in the Australian Register of Therapeutic Goods (ARTG) in order for its lawful supply in the Australian market.

Legal supply in Australia (inclusion on the ARTG)

Once a certificate is issued to a manufacturer, sponsors can:

1. lodge the new certificate as Manufacturer's Evidence (ME); and
2. apply for the inclusion of the device(s) in the ARTG using the ME to support the medical device inclusion application(s).

A medical device cannot be lawfully supplied in Australia unless the Australian Sponsor holds a current ARTG entry for the device. Please note that instructions for submitting the Manufacturer's Evidence and for making applications for medical device inclusion are provided to applicants when the certificates are issued.

Please note:

- Applications for ME take up to 15 TGA working days to process.
- Applications for inclusion of medical devices in the ARTG may be made upon acceptance of the ME and can take up to 5 TGA working days to process when TGA certificates are used as ME.
- ME applications supported by TGA Conformity Assessment Certificates and applications for inclusion of the device(s) in the ARTG are processed by the Devices Application Section of MDAB.
- Should certificates be reissued by the delegate (for example, following a substantial change notification or recertification application), Australian sponsors may need to submit the new certificate as a variation to their ME. Depending on the type of change, sponsors may also need to make a new medical device inclusion application or a Device Change Request application through the sponsor portal.

Substantial change notification and application

A manufacturer holding a TGA conformity assessment certificate is subject to a number of automatic conditions imposed under section 41EJ of the Act, and is required to ensure ongoing compliance with the applicable conformity assessment procedures. One of the conditions imposed is that the manufacturer must notify the TGA of any plan for substantial changes to:

a. quality management systems

b. the product range covered by those systems

c. the product design of kinds of medical devices

Substantial change notification and application can be made using the e-Business system. Please note that, **at a minimum**, changes to any of the following constitute a 'substantial change':

- changes to any detail on the certificate including manufacturer's name or address
- changes to device category, or to unique product identifiers
- additions or deletions of new critical suppliers
- changes to critical processes (for example, change of sterilisation method)
- changes to manufacturer's 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
- changes to the formulation of the IVD reagent that impacts on the device's safety and performance
- changes stability aspects of the IVD reagent (extension / updates to on-board stability)
- extension to specimen stability claims such as to include cadaveric specimen testing using infectious disease assays
- changes to an existing kind of device to include a new immunohaematology reagent (IHR)

For further guidance on Substantial changes affecting a TGA conformity assessment certificate, refer to Changes affecting TGA-issued conformity assessment certificates on the TGA website.

Recertification of an expiring certificate

Applications for recertification should be made at least six months prior to expiry of the manufacturer's Conformity Assessment Certificate(s).

The TGA endeavours to remind applicants about upcoming certificate expiries in time for recertification applications to be processed. However, it is the responsibility of the manufacturer to ensure that contact details in the e-Business portal are kept up to date and that recertification applications are made in sufficient time for the application to be completed and new certificates to be issued.

Once new certificates are issued, Australian sponsors may need to submit the new certificate as a variation to ME. Depending on the change, sponsors may also need to make a new medical device inclusion application or a Device Change Request application through the sponsor portal.

Further information

Enquiries relating to medical devices

Applicants are encouraged to review information on the medical devices page on the TGA website.

Alternatively, contact the Medical Devices Information Unit, Medical Devices Authorisation Branch:

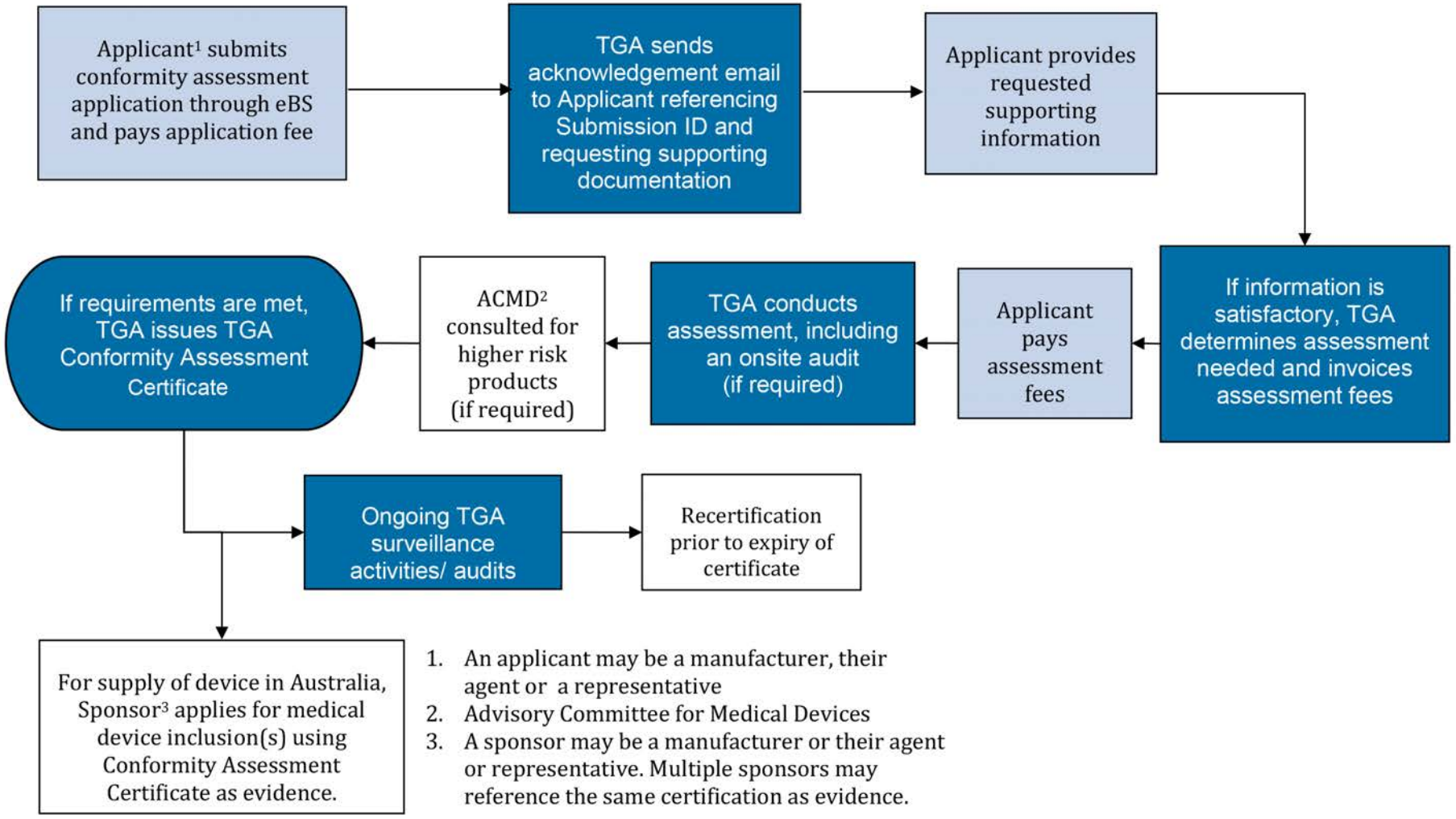
- Phone: 1 800 141 144
- Email: devices@health.gov.au

Providing feedback

Please send comments or suggestions for improvement about these instructions to devices@health.gov.au.

Application process flowchart

Flowchart describing the application process for conformity assessment certification



1. An applicant may be a manufacturer, their agent or a 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.

Version history

Version	Description of change	Author	Effective date
V1.0	Most recent version prior to inclusion of Change History section.	Office of Devices Authorisation	15/11/2010
V1.1	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.	Office of Devices Authorisation	01/12/2010
V1.2	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*	Office of Devices Authorisation	12/05/2011

Version	Description of change	Author	Effective date
V1.3	Updated section *Formatting Instructions for Supporting Data* to state that all supporting data and documents must be provided in a readable electronic format. Multiple minor grammatical alterations. Addition of link to TGA guideline for medical device assessment fee reduction.	Office of Devices Authorisation	07/11/2012
V1.4	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.	Devices Authorisation Branch	27/04/2015
V1.5	Update of links and images to reflect current eBS portal. Update to Branch Name. Update to include fees in relation to type examination and supplementary assessment. Multiple minor grammatical alterations.	Medical Device Authorisation Branch	09/12/2020

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Reference/Publication D20-3656926