



This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at
<<https://www.tga.gov.au/treatment-information-provided-tga>>.

Instructions for completing a Certificate for paragraph 41EC (3) (a) of the *Therapeutic Goods Act 1989*

This certificate must be properly completed and accompany an application form approved by the Secretary, or delegate, under paragraph 41EB (1)(a) of the *Therapeutic Goods Act 1989* for an application for a Conformity Assessment Certificate.

In deciding whether to issue a Conformity Assessment Certificate under Section 41EC of the *Therapeutic Goods Act 1989* (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.

Paragraph 41EC (3)(a), and all other provisions of the Act, may be viewed through the TGA website at <<https://www.tga.gov.au>> or at <<https://www.comlaw.gov.au>>.

All applicants for a Conformity Assessment Certificate are expected to self-assess whether they, or certain other persons associated with the applicant, meet the criteria set out below which reflects the criteria set out in paragraph 41EC(3)(a) of the Act, and to certify the outcome by submitting this Certificate to the Therapeutic Goods Administration (the TGA).

Steps to submitting this certificate

1. Carefully read the relevant provisions of the Act, and these instructions, and ensure you understand the purpose of this Certificate. Make any enquiries necessary in order to answer the matters set out in this Certificate;
2. Complete the required details and sign and attach any additional information. The signatory must mark the relevant box to either certify (i.e. "I hereby certify that"), or signal their inability to certify (i.e. "I am unable to certify"), when completing the document. Marking both boxes invalidates the certification.
3. To reduce processing times, please send the completed Certificate by email to dcas@tga.gov.au. Please ensure that your email identifies the tracking number of the associated Conformity Assessment Certificate application.

Note the signatory must:

- if the applicant for a Conformity Assessment Certificate is an individual, be that individual; or
- if the applicant for a Conformity Assessment Certificate is a body corporate, hold a senior position in that body corporate (e.g. Chief Executive Officer or Managing Director) and be authorised to make the certification on behalf of the body corporate.

Where an application for a Conformity Assessment Certificate has already been submitted, applicants should also include in their email the relevant Submission ID for that application.

Further information

Under subsections 41JA(1A) and 41JB(1) of the Act the Secretary, or delegate, may, by written notice, require an applicant for a Conformity Assessment Certificate to give the Secretary, or delegate, further information concerning the application, within a reasonable time as is specified in the notice.

Avoiding an invalid certificate

Your Certificate will not be considered to be valid if this Certificate:

- is not used;
- is incomplete;
- is unclear or ambiguous;
- has not been signed by the appropriate person (refer to the Note above); or
- has been submitted more than a month since the date of its signing.

Privacy Information

- For general privacy information, go to <<https://www.tga.gov.au/privacy>>.

Personal information in applications relating to Conformity Assessment Certification:

- The personal information is used to maintain a record of Conformity Assessment Certificate applications, to consider applications, and to contact applicants about their application.
- Personal information provided in applications may also be used to contact sponsors or manufacturers of goods in the Register where there is a need to do so – for example, in the event of a safety, quality or efficacy issue concerning the manufacture of certain goods, or to administer fees and payments relating to the licence.
- Personal information relating to manufactures who hold Conformity Assessment Certificates to manufacturer therapeutic goods may be disclosed where authorised or required by an Australian law, Court or Tribunal order; or with the consent of the person the information is about.

Note: A “major interest holder” of a body corporate means a person who:

- (a) is in a position to cast, or control the casting of, more than one-fifth of the maximum number of votes that might be cast at a general meeting of the body corporate; or
- (b) holds more than one-fifth of the issued share capital of the body corporate (excluding any part of that issued share capital that carries no right to participate beyond a specified amount in a distribution of either profits or capital).

Note: A holder of a Conformity Assessment Certificate on or after 1 December 2009 may be required by the Secretary, or delegate, to complete (by self-assessment), and submit to the TGA, a “Certificate for subsection 41JA (1C) of the Act”; to be used by the Secretary, or delegate, in deciding whether to revoke or suspend a Conformity Assessment Certificate, if the Secretary, or delegate, believes this is necessary.

Certificate for paragraph 41EC (3) (a) of the *Therapeutic Goods Act 1989*

I, _____ 1
hold the position of _____ 2
in _____ 3
at _____ 4

EITHER

hereby certify that, in relation to the application for a Conformity Assessment Certificate,

_____ 5 **dated**

none of the following people:

- i. the applicant for the Conformity Assessment Certificate (the Applicant);
- ii. a person (a manager) who makes, or participates in making, decisions that affect the whole, or a substantial part, of the Applicant's affairs;
- iii. if the Applicant is a body corporate, a person who is a major interest holder of the body corporate;

has, within the 10 years immediately before this application:

- iv. been convicted of an offence against the *Therapeutic Goods Act 1989* (the Act) or a corresponding State law; or
- v. been convicted of an offence against a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or
- vi. been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of the Act or a corresponding State law; or
- vii. been ordered to pay a pecuniary penalty for the contravention of a civil penalty provision of a law of the Commonwealth or a law of a State or Territory involving fraud or dishonesty; or
- viii. breached a condition of a Conformity Assessment Certificate; or
- ix. had a Conformity Assessment Certificate suspended or revoked; or
- x. been a manager, or major interest holder, of a body corporate in respect of which paragraphs (iv), (v), (vi), (vii), (viii) or (ix), noted above, applied in that 10 year period, if the conduct resulting in that paragraph applying occurred when the person was a manager or major interest holder of the body corporate.

OR

I am **unable** to certify that paragraphs (iv) - (x) can be met as set out above (please attach supporting information if this option is chosen).

¹ Insert full name of individual, or CEO / Managing Director / or equivalent of applicant.

² Insert position title of applicant

³ Insert applicant name

⁴ Insert applicant street address

⁵ Insert submission ID for corresponding conformity assessment application

I hereby declare that the above information is true and correct:

Full name (printed)		
Signature		Date

Witness full name		
Witnessed by (Signature)		Date

Note: Giving false or misleading information is a criminal offence under the Criminal Code.