



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Researcher considerations for medical devices

Meeting the evidence requirements for market  
authorisation

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**TGA** Health Safety  
Regulation

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# Contents

<b>About this guidance</b>	<b>4</b>
<b>Medical device life-cycle</b>	<b>4</b>
Stages of the medical device life-cycle	4
<b>Design and development phase</b>	<b>6</b>
Essential principles	6
Classification of medical devices	7
Compiling data related to your device	7
Direct versus indirect evidence	8
Clinical evidence	9
Literature review	11
<b>Guide to compiling your clinical evidence</b>	<b>12</b>
STEP 1: Compile available clinical or analytical data	12
STEP 2: Evaluate and assess your data	12
STEP 3: Design and conduct further clinical investigations	15
STEP 4: Present your analyses in a clinical evaluation report	15
<b>Pre-market (application preparation) phase</b>	<b>17</b>
Conformity assessment	17
Roles and responsibilities with conformity assessment	18
Conformity assessment certificate	18
Use of international conformity assessments	18
Implications for higher-risk medical devices	18
Market authorisation requirements	19
Additional data requirements for funding applications	19
<b>Other relevant guidance</b>	<b>19</b>
<b>More information</b>	<b>20</b>

## About this guidance

This guidance assists researchers of new medical devices, including in vitro diagnostic (IVD) medical devices and software as a medical device (SaMD), to understand the evidence requirements for market authorisation.

To eventually supply a medical device, sponsors need to submit a market authorisation application to the Therapeutic Goods Administration (TGA) to include their medical device in the [Australian Register of Therapeutic Goods \(ARTG\)](#).

This guidance provides:

- a [summary of the medical device life-cycle](#)
- an [overview of what to consider during the design and development phase](#)
- an [overview of the pre-market \(application preparation\) phase](#)
- a [guide to compiling your clinical evidence](#)

Only therapeutic goods can be entered in the ARTG. If you are unsure whether you have a therapeutic good, use the [Is my product a therapeutic good?](#) decision tool on the TGA website.

For more information about the regulation of medical devices, see the [Australian Regulatory Guidelines for Medical Devices \(ARGMD\)](#).

## Medical device life-cycle

If you wish to manufacture or supply a medical device, you are required to fulfil certain regulatory requirements throughout the product life-cycle to ensure it is safe to use and performs as intended.

### Stages of the medical device life-cycle

There are regulatory actions associated with all nine stages of the product's life-cycle. These stages are summarised in the table below.

Stage	Required regulatory action	Phase
Concept	Consider the <a href="#">essential principles</a> before you start and throughout the life-cycle.  Determine the <a href="#">classification of medical devices and IVDs</a> to inform you of the conformity assessment procedures you need to comply with.	Design and development
Prototype	Incorporate the essential principles and risk management into the design.	
Pre-clinical	Gather applicable evidence (such as bench test data, and validation or verification tests) to demonstrate that the product meets the essential principles and the generally acknowledged state-of-the-art (such as applicable standards).	

Stage	Required regulatory action	Phase
Clinical	<p>Use the <a href="#">Australian clinical trial handbook</a> for guidance on conducting clinical trials in Australia.</p> <p>Seek approval from the <a href="#">Human Research Ethics Committee</a> to run your clinical trial.</p> <p>Seek approval from or notify TGA of your intention to use your device in your clinical trial. Use the '<a href="#">Which clinical trial scheme should I choose?</a>' decision tool to help you determine the most appropriate scheme for your trial.</p> <p>Use the <a href="#">Clinical evidence guidelines: medical devices</a> to help prepare your clinical evidence.</p>	Pre-market (application preparation)
Manufacturing	<p>Apply <a href="#">conformity assessment</a> procedures and then obtain appropriate conformity assessment evidence. Consider:</p> <ul style="list-style-type: none"> <li>• <a href="#">comparable overseas regulators for medical devices</a></li> <li>• <a href="#">quality management systems standards</a></li> </ul>	
Supply	<p>Apply to TGA for <a href="#">market authorisation</a> for your device to be included in the ARTG.</p> <p>See <a href="#">Medical device inclusion process</a> for detailed information.</p>	Application processing
Marketing	<p>Adhere to the <a href="#">therapeutic goods advertising code</a>.</p>	
Post-market	<p>After a device has been included in the ARTG and supplied to the market, sponsors have post-market responsibilities including:</p> <ul style="list-style-type: none"> <li>• monitoring safety and performance of the device during its lifetime</li> <li>• reporting any problems with the device to TGA and to the users of the device</li> <li>• recalling and/or correcting devices that have defects, design flaws, or unacceptable clinical risks or levels of performance</li> <li>• submitting annual reports (if required)</li> <li>• reporting adverse events, developing corrective and preventative actions, and if required, updating product labelling and risk management documents</li> <li>• maintaining the currency of their ARTG inclusion</li> <li>• participating in recall actions as required</li> </ul> <p>See the 'post-market' tab in the <a href="#">ARGMD</a> for more information.</p>	Post-market
Obsolescence	<p>Notify TGA so the device can be removed from the ARTG.</p>	Removal of product



This guidance focusses on the [Design and development](#) and [Pre-market \(application preparation\)](#) stages of the life-cycle which concern research considerations for medical devices.

For more information on later stages, please see the [ARGMD](#).

## Design and development phase

The [essential principles](#) are foundational to the medical device life-cycle and it is important that you reference them when developing your evidence. Addressing the essential principles from the outset ensures that:

- participants in a clinical trial (where applicable) are not subjected to potentially harmful conditions
- you don't waste time and money later on redesigning and repeating your study to demonstrate your applicability for market authorisation

You also need to understand the [classification of your medical device](#), as this will inform how much evidence you will need to provide.

## Essential principles

The [essential principles](#) are 15 principles mainly about the design, safety and performance characteristics that all medical devices need to meet, and form the foundation of each stage of the medical device life-cycle. The essential principles are specified in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#).

The essential principles consist of:

- six general principles that apply to all devices
- nine design and construction principles that apply to devices on a case by case basis



TGA has an [essential principles checklist](#) that details all 15 principles. This list can help you to compile the relevant data for your application.

Complying with certain standards and documents can demonstrate compliance with relevant essential principles, such as:

- Legislative instruments published by TGA such as Therapeutic Goods Orders, Medical Device Standards Orders and/or Conformity Assessment Standards Orders
- State-of-the-art American Society for Testing and Materials (ASTM) and International standards (ISO) such as ISO 10993 (Biological evaluation of medical devices), ISO 14971 (Medical devices – Application of risk management to medical devices) and ASTM F2119–07 (Magnetic resonance image artefacts)
- Device specific standards such as ISO 5870 for cardiovascular implants or ISO 10555 for intravascular catheters

- IVD procedures such as Clinical Laboratory and Standards Institute (CLSI) Measurement procedure: comparison and bias estimation using patient samples
- Guidance documents published by the TGA and other comparable overseas regulators and published scientific literature

See the [ARGMD](#) for more information regarding standards and guidance.

## Classification of medical devices

The amount of evidence required depends on the [risk classification of your device](#). For a higher risk medical device, you will be required to provide more information than for a lower risk device.



Use the decision tool '[What classification is my medical device?](#)' on the TGA website to help you determine the classification of your medical device.

You can find further information on medical device classifications in the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#).

For higher risk medical devices, we place more emphasis on information available at the earlier life-cycle stages before supply (Stage 7). For low risk devices, we place greater emphasis on information available at the post-market stage (Stage 8).

## Compiling data related to your device

The quality and completeness of the information you include in a market authorisation application may be different to the information you might submit for a journal publication.

When developing your device, you need to ensure your data is robust and statistically significant and be able demonstrate that your device is effective. Ensure you have addressed the safety, performance and manufacturing requirements set out by the [essential principles](#). This includes clinical evidence that is appropriate for the risk classification of the device that supports the intended use of the device.



Clinical evidence is particularly relevant to essential principles 1, 3, 4, 6, 13, 14 and 15, where Essential principle 14 contains the overarching principle:

“Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the Essential principles.”

You can find examples of clinical evidence that demonstrate conformity to the essential principles in section 1 of the [Clinical evidence guidelines: Medical devices](#).

You will need to compile available clinical data (and analytical data for an IVD medical device).

See [Clinical evidence guidelines: Clinical data](#) for more information.

## Direct versus indirect evidence

You can present both direct and indirect clinical evidence in your application.

- **Direct clinical evidence** is derived from the device under evaluation. It gives the highest level of confidence in its relevance and capacity to demonstrate the safety and performance characteristics of the device.
- **Indirect clinical evidence** is derived from a predicate or similar marketed device. It may provide a benchmark for acceptable risk of the device under assessment. You need to compare similarities and differences in clinical, technical and biological characteristics, and provide reasoned justification as to why the safety and performance of the similar device may be substantially equivalent to the device under evaluation.

See [Clinical evidence guidelines: Demonstrating substantial equivalence](#) for more information.



You need to make it explicitly clear whether you are using direct or indirect data.

It is also important to clarify the exact version of the device and document whether any changes have been made to the device since the clinical data was collected.

## Clinical investigation data

You can conduct clinical investigations (synonymous with trials or studies) in Australia or outside Australia.

Clinical investigation data includes:

- documentation related to the design, approval, conduct and results of each investigation carried out by the manufacturer of the device in relation to the use of the device in or on a human body
- a record of qualitative or quantitative information obtained through observation, measurement, tests or any other means used to assess the operation of the device
- a written report by an expert in the relevant field, being a report that contains a critical evaluation of all the clinical investigation data held in relation to the device



TGA is **not** involved with the design of and approval to run clinical investigations.

We are, however, responsible for giving approval for you to **use your device** in clinical investigations.

Within Australia, you can conduct a clinical investigation under either a [notification or exemption scheme](#) for devices not currently included on the ARTG or to extend the use of a medical device beyond the conditions of current market approval.

You will need to satisfy certain reporting standards depending on what type of clinical investigation you are conducting (for example, a randomised controlled trial, observational study or diagnostic accuracy study).

See [Clinical evidence guidelines: Clinical investigation data](#) for more information.

### ***Feasibility (pilot) studies***

Feasibility (pilot) studies are clinical investigations that are used to capture **preliminary** information on a medical device at an early stage of product design. They are often used to plan further steps of device development and modification, and the endpoint is generally based on safety and performance rather than comparisons with other products.

Like any clinical investigation, you may conduct feasibility studies through either scheme if your device is not yet included on the ARTG. These studies form an important part of the evidence in your application, so conduct them in such a way that the data is of sufficient quality to be useful. Make sure they address Essential principle 2 (Design and construction of medical devices to conform to safety principles) and Essential principle 7 (Chemical, physical and biological properties).

Any clinical investigation that does not address these principles could be considered unethical, and could potentially place your participants at risk.

### **Clinical experience**

Data from clinical experience is generally post-market data, and can help substantiate the safety and performance claims of your device. It is particularly useful when your clinical investigation and literature review data is not sufficiently robust to establish a favourable benefit-risk profile of your device.

Post-market data includes:

- adverse events and complaints
- product recalls and cancellations
- device registries
- published literature
- regulatory approval in other jurisdictions

See [Clinical evidence guidelines: Post-market data](#) for more information.

### **Clinical evidence**

Medical devices are used for human health and therefore require clinical evidence to demonstrate an appropriate level of safety and performance in humans when used for its intended purpose.

Clinical evidence for a medical device comprises all of the data and information that informs expectations with regards to the safety, performance and validity of the device when it is used as intended by the manufacturer. The detail and extent of the clinical evidence will depend on:

- the risk classification of the device
- its nature or design
- the purpose for which it is intended

Clinical evidence must always include clinical safety and performance data and information, but can also include pre-clinical and analytical data derived from bench testing of a device. Clinical performance data can be derived from clinical studies and literature reviews and through post-market clinical follow-up and vigilance activities.

Clinical evidence is described differently depending on the [kind of medical device](#). Some medical devices will also need evidence of user testing in order to demonstrate that they comply with the essential principles. For example, self-testing IVD medical devices need to comply with Essential principle 15.

## Different components of clinical evidence

Different components of clinical evidence for different kinds of medical devices are listed in the table below.

Medical devices	IVDs	SaMD
State-of-the-art	Scientific validity	Clinical safety
Clinical safety	Clinical performance	Clinical performance
Clinical performance	Analytical performance	User testing
	Clinical utility	
	User testing*	

\*for IVD medical devices intended for patient self-testing

You should periodically update and systematically review your clinical evidence as new information from post-market surveillance activities and product experience becomes available.



A manufacturer is required to hold clinical evidence for a device for the entire period it remains on the ARTG. We may request and review this clinical evidence at any time.

For more information see [Clinical evidence guidelines for medical devices](#) and the [ARGMD](#).

## Clinical Evaluation Report (CER)

You will need to compile your clinical evidence into a clinical evaluation report (CER).

The CER collects, appraises and analyses the clinical data, and analytical data for an IVD medical device, to demonstrate compliance with the relevant essential principles.



TGA has published [Clinical evidence guidelines: Medical devices](#), which outline the clinical evidence requirements for medical device applications, including the recommended structure of the clinical evaluation report.

You can also refer to the European Commission's [MEDDEV 2.7/1 revision 4](#) guidelines on medical devices, upon which the TGA clinical evidence guidelines are based.

More detailed information about CERs can be found below in our [guide to compiling and providing clinical evidence](#).

## Literature review

A literature review is a compilation and analysis of published and unpublished scientific literature relating to your device when used for its intended purpose. This includes both favourable and unfavourable information regarding safety, performance, hazards and associated risks, and foreseeable misuse.

A comprehensive literature review should include the following:

- A **search protocol** to identify, select and collate relevant literature. It should describe the method used to extract data from the included studies and any processes for confirming data extracted by investigators. Your protocol must be detailed enough for a clinical assessor to reproduce the search.
- A clear explanation of your **selection strategy**. Your selection methods need to be comprehensive and transparent for our assessors to evaluate quality and lack of bias. Don't cherry pick the literature to only include favourable data. Any omission of contradictory publications or information about competitor products will likely be detected.

We strongly recommend the use of objective, non-biased, systematic search and review methods, such as:

- Preferred Reporting Items for Systematic reviews and Meta-Analyses ([PRISMA](#))
- Meta-analysis of Observational Studies in Epidemiology ([MOOSE](#))



Include a **flow diagram** to present your literature review. Detail each step in the screening process, including the total numbers of studies that are screened, assessed for eligibility and included in the review. See [PRISMA](#) and [CONSORT](#) for flow diagram templates.

- A summary and critical analysis of the literature. Tabulate and summarise the findings in your studies, including information such as effect size estimates and confidence intervals.

This summary then needs to be supplemented by a critical analysis, which appraises the data in terms of its scientific validity, relevance and weighting, as well as the analysis of the data sets to determine what conclusions can be drawn about the performance and safety of your device.

We recommend you keep each literature topic separate. For example, you may want to present clinical investigation data, and then present information relating to the state of the art for the kind of device. Present and analyse these topics separately, clearly identifying their purpose.

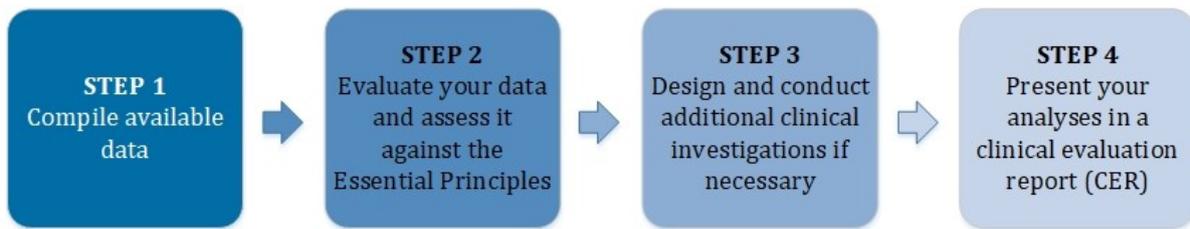
- A comprehensive literature report prepared by researchers skilled in systematic review methods.

The report also needs to be critically appraised and endorsed (evidenced by signature and date) by a competent clinical expert. They should have relevant clinical medical qualifications, and preferably direct clinical experience in the use of the device (or device type) in a clinical setting.

See [Clinical evidence guidelines: Literature review](#) for more information.

# Guide to compiling your clinical evidence

Compiling clinical evidence can be simplified into four steps:



## STEP 1: Compile available clinical or analytical data

Compile data relating to your device, including:

- analytical investigation data
- clinical investigation data (your own data obtained through your own clinical investigations)
- a literature review (including other people's data)
- clinical experience (usually post-market data)

These data types are briefly described below. See [Clinical evidence guidelines: Clinical data](#) for more information.

## STEP 2: Evaluate and assess your data

The next step is to evaluate your data and perform a gap analysis to assess whether you have sufficiently demonstrated compliance with the essential principles.

Data to assess may include (where relevant):

- material quality and safety data
- biological safety data
- pre-clinical data (animal studies)
- engineering and bench testing data
- sterilisation validation data
- manufacturing process and validation or critical processes
- packaging integrity and packaging validation
- shelf-life validation
- risk management documentation

## Evaluate your clinical data

The data derived from your analytical and clinical investigations, literature review and clinical experience needs to be evaluated to:

- find potential sources of bias that may influence the results presented in the investigations and literature
- determine weighting for the data based on the relevance and quality

Several quality appraisal tools are available online. Select a tool which is appropriate for the study design of every study in the literature sourced. Commonly used quality appraisal tools include:

- [Jadad Score](#) for randomised studies
- [Downs & Black](#) for randomised and non-randomised studies
- [QUADAS](#) for studies of diagnostic accuracy
- [AMSTAR](#) for systematic reviews

See [Clinical evidence guidelines: Evaluation of the clinical data](#) for more information.

## Determining relevance

When determining the relevance of your data, consider the following factors:

- To what extent is the data representative of the device under evaluation? Have you provided evidence relating to?
  - the device under evaluation
  - equivalent and benchmark devices
  - other devices and medical alternatives
  - data concerning the medical conditions managed with the device
- Have you covered all the important factors? For example:
  - safety
  - performance
  - hazards, risks and side-effects
  - the state of the art
  - determination of equivalence

- Have you included data related to:
  - different models, sizes or settings for the device
  - users of the device (for example, general practitioners, nurses, lay persons)
  - medical indications (for example, to treat migraines)
  - different sample types (for IVD medical devices)
  - appropriate age groups and genders
  - duration of application or use
  - the requirement of short-term and/or long-term studies



### Look for pivotal data

Data is considered to be pivotal if it is robust, statistically significant, and can directly demonstrate adequate analytical and clinical performance and clinical safety of the device under evaluation. Pivotal data is highly relevant and should be given **greater weighting**.

It can be **directly** generated from the device under evaluation, or **indirectly** from a demonstrated equivalent device used with the same intended purpose.

See the European Commission's [MEDDEV 2.7/1 revision 4](#) guidelines (Section 9.3.2) for more information.

### Perform a gap analysis

It is important to assess your data against the essential principles to identify whether there are any gaps that need to be addressed. This will allow you to determine whether you need to carry out any additional analytical or clinical investigations.

Being precise in your analysis and selecting relevant medical indications and target populations for example may reduce the amount of clinical data you'll need from additional clinical investigations.

See the European Commission's [MEDDEV 2.7/1 revision 4](#) guidelines (Section 10.2) for more information.

## STEP 3: Design and conduct further clinical investigations

You may find that additional clinical investigations are required for the device under evaluation, or even other devices and associated materials.

It is your responsibility to design and conduct any additional clinical investigations according to the principles that need to be addressed.

### Case study: Donna and the jaw implant

Donna has developed a novel jaw implant to be used in plastic surgery. She would like to conduct a feasibility study using this device.

It shares the same basic principles as other jaw implants, but it uses different materials which are not currently used by other implants on the market. She has not been able to find any safety data related to the material's use in human subjects.

Donna's jaw implant is using materials that have not been previously approved for use in any products on the ARTG. There is potential risk of harm, especially because devices like these are designed to be implanted in the body for a long period of time.

Donna's feasibility study will only be permitted if she can demonstrate that the device will not have a high risk of adverse reactions when used in humans, or be at risk of failure.

She needs to provide evidence to address any essential principles that may be related to the use of new materials. In particular, Essential principle 2 refers to the chemical, physical and biological properties of the device. There must be compatibility between the materials used and biological tissues, cells, body fluids and specimens.

Donna realises she must design and conduct a new clinical investigation to address this gap in her data. She may use data derived from the jaw implant itself, or from predicate devices, provided she can also demonstrate equivalence.

## STEP 4: Present your analyses in a clinical evaluation report

After your data has been compiled and analysed, you must complete a **clinical evaluation report (CER)** which details:

- the scope and context of the evaluation
- the clinical data (and analytical data for an IVD medical device), analysis and conclusions reached about performance, safety and presentation of the medical device when used for its intended purpose

This is a complete report that thoroughly and critically evaluates your data. It is not simply a summary of the data, followed by a statement that the data demonstrates safety and performance. It is expected that the clinical expert will evaluate all the clinical data and provide a reasoned argument as to how the data constitutes valid clinical evidence, demonstrates the safety and performance of the device and establishes a satisfactory risk-benefit profile for the device when used for the intended purpose(s).



Remember that once the medical device is marketed, the CER needs to be updated throughout the device's life-cycle to incorporate new evidence, including post-market data and updated risk/benefit analyses.

## Use the standardised report structure

We recommend you use the standardised report structure so we can assess and review your application more effectively and efficiently.

1. Device description, lineage and version (if applicable)
2. Intended purpose/indications and claims
3. Regulatory status in other countries
4. Summary of relevant pre-clinical data
5. Demonstration of substantial equivalence (if applicable)
6. Overview and appraisal of clinical data
7. Critical evaluation of clinical data (including post-market data)
8. Risk-benefit analysis
9. Conclusions
10. The name, signature and curriculum vitae of the clinical expert and date of report

See [Clinical evidence guidelines: Content and format of the report](#) for more information on the different report sections.

## Make sure your CER is endorsed by a clinical expert

Your CER needs to be endorsed by a **competent clinical expert**, who is considered to be someone with relevant clinical medical qualifications, and preferably has direct and recent clinical experience in the use of the device (or device type) in a clinical setting.

Selection of a clinical expert will depend on the type of device under assessment and its intended purpose. For example, for a coronary stent submission the clinical expert should be an interventional cardiologist.

The full curriculum vitae of the clinical expert should be included, with any convergence of interests or potential for conflict with the manufacturer or sponsor noted.

See [Clinical evidence guidelines: Clinical expert](#) for more information.

## Include supporting documents supplied with the device

Other information on the device must also be provided with the CER, including:

- risk assessment and management documents
- instructions for use, labelling, product manual and all other documents supplied with the device
- the full text of pivotal articles from your literature review

See [Clinical evidence guidelines: Supporting documents](#) for more information.

## Common problems with CERs

Be mindful of and try to avoid the common mistakes below when compiling your CER:

- Gaps in the required documentation
- Unclear or conflicting intended purpose of the device
- An undocumented literature review strategy with very little or absent critical assessment of the data
- Clinical experts who are considered inappropriate (for example, engineers with no clinical or medical education, or medical practitioners in a specialty unrelated to use of the device)
- Citing a multitude of publications without assessing their relevance or importance
- The absence of data relating to a device's use in practice when it has been marketed overseas for years
- More than one CER

## Pre-market (application preparation) phase

### Conformity assessment

[Conformity assessment](#) is the ongoing examination of evidence and procedures to ensure that a medical device complies with the [essential principles](#).

Conformity assessment involves assessment of the manufacturer's quality management system (QMS). This includes review of the technical documentation for:

- the design and development of the device
- manufacturing processes
- risk analysis
- clinical evidence, including ongoing monitoring and vigilance procedures that will be in place once the device is available for supply

Before you make a market authorisation application, you will need to submit a copy of the manufacturer's conformity assessment certification (manufacturer's evidence).

You must be able to demonstrate that you have applied the appropriate conformity assessment procedures to your medical device in order to apply for market authorisation.



Manufacturer's evidence can be more than conformity assessment.

See [Manufacturer evidence for medical devices and IVD medical devices](#) for more information.

## Roles and responsibilities with conformity assessment

The manufacturer is responsible for selecting the appropriate conformity assessment procedures to meet relevant regulatory requirements.

Some conformity assessment certificates must be issued by TGA (depending on the classification of the device) whilst others may be issued an equivalent certificate by an applicable Comparable overseas regulatory (COR).

Applications received by TGA will be assessed to determine whether the technical documentation provided by the manufacturer supports the quality, safety and performance of the medical device against the requirements of the essential principles in order to issue a [conformity assessment certificate](#).

## Conformity assessment certificate

A conformity assessment certificate is the evidence issued by TGA to demonstrate that a manufacturer has been assessed and has an appropriate quality management system (QMS) in place to manufacture the device.

TGA conformity assessment certificates may apply to the manufacturer (QMS certificate) or be specific to a device or kind of device (Design Examination certificate). Comparable overseas regulators (CORs) can issue equivalent evidence of assessment but these are not called conformity assessment certificates.

Once TGA or an applicable COR has issued a conformity assessment certificate or equivalent, this evidence may be used to submit an application for market authorisation.

You can find guidance on how to apply to TGA for a conformity assessment certificate at [Application for conformity assessment certificates \(medical devices\)](#).

## Use of international conformity assessments

TGA accepts a number of [comparable overseas regulators](#) and assessment bodies as providers of evidence of compliance with conformity assessment procedures.

See [Comparable overseas regulators for medical device applications](#) for the current list of comparable overseas regulators and assessment bodies.

## Implications for higher-risk medical devices

Some high-risk medical devices (including IVD medical devices) **must** have a TGA issued conformity assessment certificate. You cannot apply for inclusion of these products into the ARTG with only evidence from a COR.

Examples of high-risk devices are:

- Class III devices
- Active Implantable Medical Devices (AIMDs)
- Medical devices containing materials derived of animal, microbial or recombinant origin
- Medical devices containing medicinal substances (substances that if used separately would be considered medicines)
- Medical devices containing derivatives of human blood or plasma
- Class 4 IVD devices (including Class 4 in-house IVDs)

## Market authorisation requirements

You may need to provide [supporting documentation](#) as part of your market authorisation application.

The amount of supporting documentation you will need to include in your application depends on the classification and the kind of device you have.

For some medical devices, you will **not** be required to submit supporting documentation with your market authorisation application. These include:

- Class I medical devices (excluding IVD medical devices) that do not have measuring function, and are not intended to be supplied sterile.
- Some Class 1 IVD medical devices that are not intended to be used for self-testing or point-of-care testing.

These devices are automatically included in the ARTG, so do not require the documentation to be submitted with the application. However, you still need to have supporting documentation to provide to TGA should we request it after your product is included in the ARTG.

For detailed information on market authorisation requirements, see [Medical device inclusion process](#).

## Additional data requirements for funding applications

Some health technologies may be eligible for public funding. Assessment for reimbursement is a function of the broader Australian Government Department of Health.

When making an application for funding, you will need comparative safety and clinical data and evidence of **cost-effectiveness**, so you need to design your studies to collect this information.

For some products, you may be able to make applications to the Department of Health for subsidy or reimbursement in parallel with your application to TGA for market authorisation. However, no pharmaceutical, prosthesis or Medicare listing will occur until the product is included in the ARTG. Inclusion of your product in the ARTG doesn't automatically mean that your product or associated service will be subsidised or reimbursed.

For more information about data requirements for health funding applications:

- [Health Technology Assessment overview](#)

## Other relevant guidance

You may also find the guidance below helpful:

- [Application audit \(technical file review\) of IVD medical device applications](#)
- [Medical device cyber security guidance for industry](#)
- [Approved names for ingredients](#) and [new chemical entities](#)
- [Regulatory framework for biologicals](#)
- Information on upcoming [public consultations](#)

## More information

Email [devices@tga.gov.au](mailto:devices@tga.gov.au) or [sme.assist@tga.gov.au](mailto:sme.assist@tga.gov.au) for more information.

## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	Original publication	Regulatory Guidance, Assistance and SME Section	February 2020

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