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>.

Conformity assessment certification

Supporting data form

For manufacturers applying for one or more of the following:

- a conformity assessment (CA) certificate
- a certificate of conformity under the Australian–European Mutual Recognition Agreement (MRA) – "EC Certificate"

Applications may be made for:

- new certificates
- changes relating to existing certifications, and
- recertification of existing certificates.

ISO 13485 certificates

Australian manufacturers may apply to the Quality Audits and Assessments section, Medical Devices Branch (MDB) for a separate ISO13485:2016 certificate **after** a CA certificate has been issued by the Devices Conformity Assessment section, Medical Devices Branch (MDB).

To apply, use the form: Request for certificates or notarised copies of TGA licences and certificates.

For additional information contact QMS.Certifcates@health.gov.au

Completing the form

Please ensure

- All information is verified by the manufacturer.
- The information and data submitted:
  - is accessible and navigable (i.e. a single PDF document without bookmarks is not acceptable).
  - clearly marks the relevant documents. All documents should be easily accessed (use of electronic indexing within documents is recommended).

Failure to complete all relevant fields in this form may result in the lapsing of your application under section 41EG of the Act.

Guidance to completing the form

Applicants should refer to the:

- Australian Regulatory Guidelines for Medical Devices (ARGMD) (currently under review)
- *Therapeutic Goods Act 1989* (the Act)
- *Therapeutic Goods(Medical Devices) Regulations 2002* (the Regulations) and
- Application instructions: Conformity assessment certification.

IVD device applicants should also refer to:

- IVD guidance documents

For guidance regarding information and data requirements for a Class 4 IVD design dossier (non-IHR and IHR) please refer to:

- Application audit (technical file review) of IVD medical device applications, and
- Conformity assessment procedures for immunohaematology reagents.

Submitting the form

An electronic TGA e-Business (TBS) application using the 'Application for a conformity assessment certificate' form must be made (and application fee paid) **prior to** submitting this supporting data form **and** associated information and data. A Submission ID will be generated once the application fee has been paid. The TGA will then send the applicant a request to provide the completed supporting data form and associated documentation.

When requested, please forward a completed copy of this form, together with all relevant supporting documentation (as one electronic copy), to:

Postal Address

Devices Conformity Assessment Section
Medical Devices Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

or

Courier Delivery

Devices Conformity Assessment Section
Medical Devices Branch
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609

1. General detail

1.1. Applicant details

Applicant's business or commercial name (Client in TBS)	
Physical address	
Postal address	
Contact person (full name)	
Telephone number	
Mobile number	
Email address	
TGA Client ID	

1.2. Details for assessment fee invoicing (contact person)

Assessment fee

For the relevant fees, please refer to the Manufacturing medical devices section of the current TGA Schedule of fees and charges.

Reduced assessment fee – abridged assessment

Applicants may make a written request for an abridged assessment in some circumstances, which may result in reduced assessment fees.

For further information refer to Reduction of assessment fees for medical devices.

Full name and position for fee invoicing	
Telephone number	
Email address	

2. Application scope

Please note

Parts and clauses referred below relate to Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations).

Specify the scope of this application by selecting **one or more** of the following sections. Follow the relevant link(s) to view further instructions.

- Application for new conformity assessment certificate (Schedule 3, Part 1, 3, 4 and 5) and/or certificate for a new Unique Product Identifier (or kind of device for Class 4 IHR IVD) (Schedule 3, Clause 1.6 or Part 2) – Go to 2.1 ☐
- Application for substantial change(s) in relation to an existing conformity assessment certificate(s) – Go to 2.2 ☐
- Application for recertification of an existing conformity assessment certificate(s) – Go to 2.3 ☐
- Application for MRA EC certificate issued under the Medical Devices Directive (93/42/EEC) (Australian manufacturers only) – Go to 2.4 ☐

2.1. Application for a new conformity assessment certificate (Schedule 3, Part 1, 3, 4 and 5) and/or certificate for a new Unique Product Identifier (or kind of device for Class 4 IHR IVD)

For this type of application, you must complete:

- Section 1: General details
- Section 3: Manufacturer details
- Section 4: Critical supplier details
- Section 5: Device details (non-IVD only) or Section 6: Device details (IVD only) or both depending on your device(s)
- Attachment 1: New certificate checklist

2.1.1 Choose one or more of the following two options:

- A new conformity assessment certificate(s) (Schedule 3, Part 1, 3, 4 or 5) ☐
- New Unique Product Identifier(s) (or kind of device for Class 4 IHR IVD) (Schedule 3, Part 1, Clause 1.6 or Part 2) ☐

2.1.2 Choose the applicable conformity assessment procedure:

- Part 1 - Full Quality Assurance (**including** Clause 1.6) ☐
- Part 1 - Full Quality Assurance (**excluding** Clause 1.6) ☐
- Part 1 - Clause 1.6 **only** - Examination of Design ☐
- Part 2 - Type Examination ☐
- Part 3 - Verification Procedure (non-sterile only) ☐
- Part 4 - Production Quality Assurance ☐
- Part 5 - Product Quality Assurance (non-sterile) ☐

2.1.3 Enter a short description of the application:

2.2. Application for substantial change(s) in relation to an existing conformity assessment certificate(s)

For this type of application, you must complete:

- Section 1: General details
- Section 3: Manufacturer details
- Section 4: Critical supplier details
- Section 5: Device details – only for devices impacted by change(s)
- Attachment 2: Substantial change checklist

2.2.1 Provide certificate numbers:

Substantial change(s) to quality management system or kinds of device to which the system is applied (Schedule 3, Part 1, 3, 4 or 5).	List certificate number(s):
A substantial change(s) to the product design or intended performance (Schedule 3, Clause 1.6 or Part 2).	List certificate number(s):

2.2.2 Enter a short description of the change(s):

2.3. Application for recertification of an existing conformity assessment certificate(s)

For this type of application, you must complete:

- Section 1: General details
- Section 3: Manufacturer details
- Section 4: Critical supplier details
- Attachment 3: Recertification checklist

2.3.1 List certificate number(s) and expiry dates:

List certificate number(s):	Expiry date(s):
List certificate number(s):	Expiry date(s):

2.4. Application for MRA EC certificate issued under the Medical Devices Directive (93/42/EEC) (Australian manufacturers only)

For this type of application, you must complete:

- Section 1: General details
- Section 3: Manufacturer details (including Section 3.2)
- Section 4: Critical supplier details (including Section 4.1.1)
- Attachment 1: Final page of New Certificate Checklist

3. Manufacturer details

3.1. Manufacturer details

(* Denotes mandatory field)

Please note

TGA CA certificates are issued in electronic format via email.

Certificates will not be issued unless this information is provided.

Manufacturer's name*	
Trading name (if applicable)	
Australian Business number (ABN) / Australian Company number (ACN)	
TGA Client ID	
Manufacturer's physical address*	
Facility scope* Manufacturing stages performed at this site, e.g. design, key production steps (specify), labelling, final release, warehousing and dispatch	
Manufacturer's postal address*	
Website address e.g. 'https://www.website.com'	
Full name of contact person*	
Position of contact person*	
Telephone number of contact person*	
Email address of contact person*	

3.2. European representative (for Australian manufacturers applying for MRA EC certificates only)

Please note

MRA EC certificates are issued in electronic format via email.

Certificates will not be issued unless this information is provided.

European representative's name	
Full name of contact person	
Position of contact person	
Telephone number of contact person	
Mobile number of contact person	
Email address of contact person	
Head Office physical address	
Head Office postal address	

3.3. Manufacturer facility (site) details

Please note

If the manufacturer has more than one facility, please complete a copy of Section 3.3 for each additional facility.

All key stages of manufacture, whether undertaken in-house or by critical suppliers, should be accounted for either here or in Section 4, as appropriate.

As per manufacturer details in Section 3 of this form ☐

3.3.1. Address and contact (if different to details provided in Section 3.1)

Facility name	
Facility physical address	
Facility scope Manufacturing stages performed at this site, e.g. design, key production steps (specify), labelling, final release, warehousing and dispatch	
Full name of contact person	
Position of contact person	
Telephone number of contact person	
Email address of contact person	

3.4. Current certification details

Please note

Applicants should provide information on any relevant certificates held by the manufacturer.

Requests for an abridged assessment made on the basis of holding other relevant certification must be accompanied by copies of the referenced certificates and the most recent full (initial/recertification) audit report including any subsequent surveillance reports and, if relevant, all technical assessment reports.

3.4.1. Current TGA certification/approval held by the manufacturer

QMS CA certificate number Schedule 3, Part 1, 3, 4 or 5 of the Regulations e.g. AU Q00123	
QMS MRA EC certificate number Annex II, V or VI of the Medical Devices Directive 93/42/EEC e.g. MRA Q00100	
Design examination certificate number Schedule 3, Part 1, clause 1.6 of the Regulations e.g. AU D00123	
Type examination certificate number Schedule 3, Part 2 of the Regulations e.g. AU T00123	
Licence to Manufacture Therapeutic Goods or any other TGA certificate number	
Has the product been supplied in Australia under the Special Access scheme (SAS)?	

3.4.2. Quality management system certificates held by the manufacturer: (Example: Annex II, V or VI of Medical Device Directive 93/42/EEC (MDD) or Active Implantable Medical Device Directive 90/385/EEC (AIMDD), or Annex IV or VII of In Vitro Diagnostic Devices Directive 98/79/EC (IVDD), or Medical Device Single Audit Program (MDSAP).

Refer guidance on Use of Market authorisation evidence from comparable overseas regulators/assessment bodies for medical devices.

Applicable: ☐ Yes ☐ No

Certificate number		Approval body	
Commencement date		Expiry date	
Certificate type e.g. Annex IV			
Scope of certificate			
Facilities covered by certificate: name and address			
Conditions or limitations			
Location of certificate e.g. vol. 1, section 3, p.10			
Date of most recent audit			
Date of last full audit (initial or recertification)			
Location of reports Most recent full (initial/recertification) audit including any subsequent surveillance reports e.g. vol.1, section 3, p 10			

3.4.3. Design/type examination certificates held by the manufacturer (Example: Annex II section 4 or Annex III of MDD 93/42/EEC or AIMD 90/385/EEC or Annex IV section 4 or Annex V of IVDD 98/79/EC or Premarket Approval (FDA) or Medical Device License (Health Canada) or Product Certification (PMDA).

Refer guidance on Use of Market authorisation evidence from comparable overseas regulators/assessment bodies for medical devices.

Applicable: ☐ Yes ☐ No

Certificate number		Approval body	
Commencement date		Expiry date	
Certificate type e.g. Annex II.4, PMA			
Devices			
Conditions or limitations			
Location of certificate e.g. vol. 1, section 3, p.10			
Location of reports Most recent full (initial/recertification) audit including any subsequent surveillance reports e.g. vol.1, section 3, p 10			

3.4.4. ISO 13485:2016 certificates held by the manufacturer (IVDs only)

Applicable: ☐ Yes ☐ No

Certificate number		Approval body	
Commencement date		Expiry date	
Certificate type e.g. ISO 13485			
Scope of certificate			
Facilities covered by certificate: name and address			
Conditions or limitations			
Location of certificate e.g. vol. 1, section 3, p.10			
Date of most recent audit			
Date of last full audit (initial or recertification)			
Location of reports Most recent full (initial/recertification) audit including any subsequent surveillance reports e.g. vol.1, section 3, p 10			

4. Critical supplier details

A critical supplier delivers materials (raw or processed), components (including hardware and software), or services, that may influence the safety and performance of the device.

The following list includes examples of critical suppliers:

- Suppliers of certain types of raw materials in non-IVD medical devices, including the suppliers of medicinal substances, active ingredients, and material of animal, microbial or recombinant origin. For IVD medical devices; suppliers of critical/unique materials or components.
- Suppliers of sterilisation services.
- Suppliers of design and development activities for manufacturers holding, or applying for, a full quality assurance CA certificate.
- Suppliers that carry out any stages of production on behalf of the manufacturer.
- Suppliers that carry out a key stage of product realisation on behalf of the manufacturer (e.g. drug coating).
- The TGA may list some, or all, of the critical suppliers on a Schedule 3, Part 1, 3, 4 or 5 certificates.

Please note

In the context of a QMS inspection of a medical device manufacturer, a critical supplier is a supplier of a product or service, the failure of which to meet specified requirements could cause unreasonable risk to the patient, clinician, or others; or could cause a significant degradation in performance.

The manufacturer should determine the type and extent of controls to be applied to outsourced processes or purchased products from the risk management that is applied throughout product realisation (See clauses 7.1, 4.1, and 7.4.1 of ISO13485:2016).

Copy this section for each critical supplier:

Supplier's name	
Supplier's physical address	
Scope For each relevant device, manufacturing stages performed at this site or services provided.	

5. Device details (non-IVD devices only)

Copy this section for each kind of device

(Kind of device is defined by section 41BE of the Act and regulation 1.6 of the Regulations)

Device name(s)			
GMDN code e.g. 34179			
GMDN term e.g. bio absorbable coronary artery stent, drug-eluting			
Unique Product Identifier For Class III and Class AIMD only. For further information, refer to the ARGMD.			
List of variants For Class III and Class AIMD only. e.g. diameter and length ranges For further information, refer to the ARGMD.			
Australian classification Schedule 2 of the Regulations	Class I ☐ Class IIa ☐ Class IIb ☐ Class III ☐ AIMD ☐	Applicable Australian classification rule e.g. 3.4(4)(a)	
EU classification For MRA EC certification applications only. Annex III, IX of MDD 93/42/EEC or AIMD 90/385/EEC	Class I ☐ Class IIa ☐ Class IIb ☐ Class III ☐ AIMD ☐	Applicable EU classification rule e.g. rule 5	

What is the manufacturer's intended purpose for the device? For example: The device is intended to be used to display and/or record real-time arterial blood pressure, intracranial (inside the skull) pressure, cerebral perfusion (blood flow in the brain) pressure, temperature, respiratory (breathing) rate, electrical activity of the heart, pulsatile (pulsing) heart rate, and/or oxygen saturation (percentage of oxygen in the blood). The device is intended to be used by a clinician for the monitoring of a patient and for the diagnosis of illness or disease.	
Description of the device For example: The device comprises of the following components: • Software • Microcontroller • Battery • Hardware interface The device detects and records information on a portable hard drive. With the help of the associated PC software, the recorded information can be read and analysed by the clinician. Clinical parameters are detected via vibrations measured by the device. The devices are supplied non-sterile.	

Is the device supplied sterile?	☐ Yes ☐ No
Is the device single-use?	☐ Yes ☐ No
Does the device incorporate a measuring function?	☐ Yes ☐ No
Is the device an active medical device?	☐ Yes ☐ No
Does the device incorporate software?	☐ Yes ☐ No
Device incorporates a medicinal substance that has an action that is ancillary to the device	☐ Yes ☐ No
Device incorporates an extract from human blood or plasma that has an action that is ancillary to the device	☐ Yes ☐ No

Device incorporates material or substances of animal origin or was manufactured using materials of animal origin	☐ Yes ☐ No
Device incorporates or was manufactured using material or substances of microbial origin	☐ Yes ☐ No
Device incorporates material or substances produced using recombinant technology	☐ Yes ☐ No

6. IVD medical device details

Copy this section for each kind of IVD

Kind of medical device for IVDs is defined by section 41BE of the Act and regulation 1.6 of the Regulations. For information about the concept of kind of device m immunohematology reagents (IHR) IVDs, and Unique Product Identifiers (UPIs) and IVD closed systems for Class 4 non-IHR IVDs, refer to: Including IVD medical devices in the ARTG and Conformity assessment procedures for immunohaematology reagents.

For Class 4 IVDs (that are not IHRs) - the UPI In addition, list all IVDs within an IVD closed system (if relevant) for the UPI For Class 4 IHRs – the GMDN Collective term				
For Class 4 IHRs and Class 1, 2 or 3 IVDs - list individual device names within the GMDN Collective Term				
Classification Schedule 2A of the Regulations See Classification of IVD medical devices	Class 1 IVD ☐	Class 2 IVD ☐	Class 3 IVD ☐	Class 4 IVD ☐
	Applicable classification rule			
GMDN code and term For Class 1, 2 & 3 IVDs and all IHRs—the GMDN Collective term For Class 4 IVDs (that are not IHRs)—GMDN Preferred term See The use of GMDN codes for IVD medical devices in Australia				

What is the manufacturer's intended purpose for the kind of IVD medical device?	
Description of the device(s) Provide sufficient detail to enable differentiation between individual devices within each kind of IVD medical device	

ATTACHMENT 1: New certificate checklist

You are required to complete this attachment for:

- A new conformity assessment certificate(s) (Schedule 3, Part 1, 3, 4 or 5)
- New Unique Product Identifier(s) (or kind of device for Class 4 IHR IVDs) (Schedule 3, Clause 1.6 or Part 2)

You are required to provide the information/data location details (i.e. where the document is located within the supplied package) for each section that you select as '***Applicable - Yes***'.

For quality management system

Applicable: ☐ Yes ☐ No

Manufacturers must be able to demonstrate that a scheduled program of internal audit and management review in accordance with ISO 13485:2016-Clauses 8.2.4 and 5.6, has been defined, and undertaken, prior to an inspection. These processes must consider whether the manufacturer has implemented and complied with ISO 13485:2016 and the regulatory requirements of the target markets (e.g. Australia, Canada and the European Union.).

If an inspection of the manufacturer's QMS is required for this application, the Quality Audits and Assessments Section (QAAS) will contact the manufacturer prior to the inspection and request further relevant QMS documentation for review.

Information	Location of information in supplied supporting documentation
Overview of manufacturing stages for each device Details of the manufacturing steps, or services provided by the responsible party	
Latest version of the Quality Manual This must at a minimum include a reference to documented procedures. *ISO 13485, clause 4.2.2 and Schedule 3, Part 1.4 and 4.4 of the Regulations.*	
A description of how purchasing requirements are fulfilled for the suppliers identified at section 4 of this form This must include the supporting procedures and records of supplier evaluations by the manufacturer or suitable third party; and any agreement between the manufacturer and supplier defining responsibilities and authorities. *ISO 13485, clauses 7.4.1, 7.4.2 and 7.4.3 and Schedule 3, Part 1.4 and 4.4 of the Regulations*	
List of validated processes *ISO 13485, clause 7.5.6 and Schedule 3, Part 1.4 and 4.4 of the Regulations*	

Information	Location of information in supplied supporting documentation
For each process validation considered critical to the safety and performance of the device, e.g. drug coating process, sterilisation. Protocols/procedures for the validated process. Process validation report. The procedures for monitoring and controlling the process parameters of a validated process should be fully described. The frequency of re-validation.	
Procedures for a post-market monitoring system *ISO 13485, clauses 8.2.1 and Schedule 3, Part 1.4(3), Part 4.4(3) or Part 5.4(3) of the Regulations.*	
Procedures to notify the TGA, in writing, and arrange for assessment by the TGA in respect to proposed substantial changes to the quality management system or kinds of devices to which the system is applied, or substantial changes to the design or intended performance for Class III, AIMD and Class 4 IVDs that have undergone design examination. *Schedule 3, Part 1.5(2), 1.6(4), 4.5(2) and 5.5(2) of the Regulations*	
Procedure for the issue and implementation of advisory notices and the notification of adverse events *ISO 13485, clauses 7.2.3, 8.5.1 and Schedule3, Part 1.4(3), Part 4.4(3) or Part 5.4(3) and regulation 5.7 of the Regulations, Uniform Recall Procedure for Therapeutic Goods.*	
An undertaking (in writing) by the manufacturer to continue to comply with the requirements of the quality management system after assessment. *Schedule 3, Part 1.3(2)(e), Part 4.3(2)(e) or Part 5.3(2)(e) of the Regulations*	
An undertaking (in writing) by the manufacturer to ensure that the quality management system is at all times is adequate and efficacious. *Schedule 3, Part 1.3(2)(f), Part 4.3(2)(f) or Part 5.3(2)(f) of the Regulations*	
An undertaking (in writing) by the manufacturer to notify the TGA, or the Australian sponsor, of any information of the kind mentioned in subparagraphs 1.4(3)(c), 4.4(3)(c), or 5.4(3)(c) (for Parts 1, 4 or 5 CA procedures respectively), that the manufacturer becomes aware of in relation to the kind of medical device. *Schedule 3, Part 1.3(2)(g), Part 4.3(2)(i) or Part 5.3(2)(i) of the Regulations*	

For each kind of medical device, including those undergoing design examination

(Copy this table for each kind of medical device included in this application).

Information	Location of information in supplied supporting documentation
Risk Analysis Results of the risk analysis process conducted in accordance with ISO 14971:2012 (or an equivalent/better standard) and how the risks identified have been controlled to an acceptable level. This typically would include the latest risk management report, any associated risk analysis documentation, risk acceptability and details on how the risk acceptability criteria have been determined (i.e. by reference to clinical performance requirements according to the intended purpose of the device). Please note that reference to requirements specified in a technical standard would not normally be sufficient in itself for demonstrating the clinical justification of risk acceptability.	
Essential Principles checklist For checklist template go to Essential principles checklist (medical devices)	
Clinical evidence This should include the following: • Clinical trial data (where applicable) - including all pivotal clinical study reports in full; and/or • Clinical literature review (where applicable) - if this method of evidence is chosen, please provide: − the search strategy with sufficient detail such that the search can be replicated (e.g. document databases searched, search terms used, and inclusion and exclusion criteria applied) − pivotal publication(s) in full − sufficient detail for other publications to enable a technical assessment of the data, i.e. study design, methodology, statistics and outcome measures. • A clinical evaluation report (CER) written by an expert in the relevant field ensuring: − the CER contains an objective critical evaluation of all of the clinical data submitted in relation to the device, with particular emphasis on whether and how the clinical data demonstrates safety and performance of the device for the intended purpose/use claimed. Please note that the clinical data must be evaluated by competent clinical experts. • A complete curriculum vitae, or similar documentation, to justify the manufacturer's choice of the expert. *Schedule 3, Part 8 of the Regulations* Refer to the Clinical evidence guidelines: Medical devices	

Information	Location of information in supplied supporting documentation
Labelling and instructions for use (Essential Principle 13) For all life-sustaining implantable medical devices (including stents, AIMDs, leads, orthopaedic implants, heart valves, vascular grafts): • MR labelling showing MR conditional, MR unsafe, or MR safe in accordance with ASTM F2503-13. • Updated MR Manual or IFU including the proposed MR conditions, MRI field strength (1.5T or 3T), quantitative image artefact information, specific absorption rate (SAR) limit. New regulatory requirements for patient implant cards and device leaflets are being progressively implemented from 1 December 2018 (See Strengthening the assessment of medical devices and information for consumers).	

For Design Examination (Schedule 3, clause 1.6) certificates

Applicable: ☐ Yes ☐ No

Information	Location of information in supplied supporting documentation
Design dossier A compilation of design examination records demonstrating compliance with the essential principles. The design dossier should include documentation and records specific to the subject device that results from the implementation of the manufacturer's design and development procedures (ISO 13485:2016, clause 7.3) and should also include the elements listed in the section below where relevant to the kind of device. *Schedule 3, Part 1.6(3) and 1.4(5)(c) of the Regulations.* For guidance regarding requirements for a Class 4 non-IHR IVD design dossier please refer to Application audit (technical file review) of IVD medical device applications. For Class 4 IHRs refer to Conformity assessment procedures for immunohaematology reagents.	

Biological safety (excluding IVDs)
 	
• Overall biological safety evaluation summary document
• A list of raw materials, suppliers and evidence for quality (e.g. Certificate of Analysis) and safety of the raw materials e.g. Compliance with European Pharmacopeia (EP), British Pharmacopeia (BP), US Pharmacopeia needs to be provided.
• Full set of biological safety/biocompatibility test reports according to current relevant standards (e.g. ISO 10993). If version used is not up to date, justification of why use of the superseded version will not have detrimental impact on safety and effectiveness should be provided.
• Justification should be provided for the tests used and level of investigations performed. Where no test is performed, the rationale for not performing that test should be provided.
• In vivo non-clinical performance and safety animal study data (if applicable)
• Drug local release profiles (if applicable)
• Resorption profiles (if applicable)
• Endotoxin testing data (if applicable)
• Evidence for safety of impurities contained in the final product. The impurities can include, but not limited to:
  − Sterilisation residuals (if applicable)
  − Manufacturing residuals
  − Leachable from device components and containers	

Information	Location of information in supplied supporting documentation
Shelf life validation and packaging • Description of the proposed shelf life, storage conditions and packaging materials/configuration • Packaging validation reports • Evidence for the stability, continued functionality and safety of the device (including chemical, mechanical, physical properties and critical performance characteristics)	
Engineering (bench testing and performance) Test protocols and reports of verification and validation (V&V) testing to demonstrate claimed compliance with relevant device-specific standards, e.g.: • For all devices incorporating software V&V testing to demonstrate compliance with IEC 62304 and IEC 62366 or equivalent standard. • For all electronic and electric devices V&V testing to demonstrate compliance with IEC 60601-1 and IEC 60601-1-2 or equivalent standard. • For all heart valves V&V testing to demonstrate compliance with ISO 5840 – Cardiovascular implants – Cardiac valve prosthesis or equivalent standard. • For all passive MR conditional and safe devices V&V testing to demonstrate compliance with ASTM F2119, ASTM F2503, ASTM F2182, ASTM F2052, ASTM F2213 or equivalent standard. • For all active MR conditional devices V&V testing to demonstrate compliance with ISO 14708, ISO/TS 10974, ASTM F2119, ASTM F2503, ASTM F2182, ASTM F2052, ASTM F2213 or equivalent standard. • Or any other relevant standards.	

For all devices (excluding IVDs) containing medicinal substance(s)

Applicable: ☐ Yes ☐ No

For guidance see Section 14, Part 2, ARGMD.

Information	Location of information in supplied supporting documentation
Manufacturing quality Current GMP compliance evidences for each manufacturer that (produces/processes) the medicinal substance.	
For a new chemical entity (NCE - A chemical, biological or radiopharmaceutical substance that has not previously been included in the ARTG) Medicinal substances that are **not contained** in any product registered/included in the ARTG: · Quality data (e.g. CTD Module 3, DMF or CEP with supporting data described in Guidance 11 of the ARGPM · Non-clinical safety data (e.g. CTD Module 4)	
For non-new chemical entity Medicinal substances that are contained in a product registered/included in the ARTG · If the medicinal substance is manufactured by the same manufacturer (as other product/s already in the ARTG) − Confirmation of the substance quality − ARTG No. of the product/s containing the same medicinal substance − TGA DMF Reference No., if available (a letter from the medicinal substance manufacturer to allow TGA access to the DMF AND confirmation that the quality of the medicinal substance contained in the device has not been changed since the last update of the DMF submitted to the TGA are required) − Confirmation that the quality of the medicinal substance contained in the device is the same quality as the medicinal substance supplied for the product(s) registered/included in the ARTG · If the medicinal substance is manufactured by a different manufacturer − Quality data (e.g. CTD Module 3, DMF or CEP with supporting data described in Guidance 11 of ARGPM	

GMP = Good Manufacturing Practice; CTD = Common Technical Document; DMF = Drug Master File; CEP = Certificate of Suitability to monographs of European Pharmacopoeia.

For all devices (excluding IVDs) containing material of animal, microbial or recombinant origin

Applicable: ☐ Yes ☐ No

For guidance see Section 15, Part 2, ARGMD

Information	Location of information in supplied supporting documentation
Evidence to demonstrate compliance with Conformity Assessment Standard Order No 2 (or equivalent/better) for devices containing materials of animal origin.	
Information on controls related to sourcing/collection/handling *(ISO 22442-2)*	
Validation of the manufacturing process' capability to clear viruses. *(ISO 22442-3)*	
Risk assessment that identifies the adventitious agents that are likely to be in the stating material, estimates the concentrations likely to be present and demonstrates that the control measures in place adequately controls theses adventitious against to an acceptable level in the final product. *(ISO 22442-1)*	

For all devices (excluding IVDs) containing human blood or human plasma derived materials

Applicable: ☐ Yes ☐ No

Information	Location of information in supplied supporting documentation
Information on donor selection and testing of individual donations, minipools and plasma pools (info normally in a PMF).	
If PMF (Plasma Master File) is referenced, is a European Medicines Agency PMF certificate referenced.	
Validation of the manufacturing process' capacity to clear viruses.	
Risk assessment that identifies the adventitious agents that are likely to be in the starting material, estimates the concentrations likely to be present and demonstrates that the control measures in place adequately controls these adventitious agents to an acceptable level in the final product.	

For all IVDs (only) containing material of human or animal origin

Applicable: ☐ Yes ☐ No

Information	Location of information in supplied supporting documentation
A statement indicating whether or not the IVD medical device contains viable tissues, cells or substances of human or animal origin. *Schedule 3, Part 1.4(5)(c)(via) of the Regulations*	

For all sterile devices (excluding IVDs)

Applicable: ☐ Yes ☐ No

For guidance see Section 3, Part 1, ARGMD

Information	Location of information in supplied supporting documentation
For terminally sterilised products, information showing that the process has been physically and microbiologically validated to a SAL of 10^{-6}. This should include: • The method of sterilisation used and the parameters (validation and routine) • A clear statement as to the standards being applied and/or details of any alternative sterilisation validation method used, if not specified in a recognised standard • The pre-sterilisation bioburden limit, the bioburden method used and validation of the method • A report describing the initial validation of the process and information/reports on revalidations carried out • Method of batch release i.e. BI release, sterility testing, dosimetric release or parametric release	
For products that are manufactured using sterile filtration and aseptic filling or aseptically manufactured: • bioburden information including pre-sterilisation bioburden limits and for extended processing times, evidence to show that microbiological quality (before sterilising filtration) and sterility (after sterilising filtration) is not compromised • parameters of sterilisation processes applied to the containers and closures and evidence to show that these processes have been physically and microbiologically validated to a SAL of 10-6 • details of filter integrity testing and information to show that the sterilising filter has been validated for bacterial retention in the presence of the product • statements of maximum permitted processing times during manufacture (holding, storage and filling times) • media fill studies to validate the aseptic manufacturing process. Media fill studies should be conducted under worst case conditions including maximum processing and filling times and should include simulation of all aseptic manufacturing processes • details of batch release sterility testing	

Information	Location of information in supplied supporting documentation
For products that are intended for multi-dose use: • information on antimicrobial preservative efficacy data at the beginning and end of the closed shelf life • information on microbiological challenge testing/simulated use testing to support the open shelf life (in-use period)	
Sterilisation residue report(s), where applicable.	

For all reusable devices (excluding IVDs)

Applicable: ☐ Yes ☐ No

Information	Location of information in supplied supporting documentation
Details of cleaning instructions and sterilisation method/process instructions	
Validation reports of the cleaning procedure and sterilisation process	
Information to be provided by the manufacturer for the processing of re-sterilisable medical devices to demonstrate compliance with EN ISO 17664 or equivalent or better standard	

For all devices (including IVDs) – Regulatory history in Australia and other countries

A concise summary of post market performance information, including:	Location of data in supplied supporting documentation
Adverse events (reportable for EU/TGA/other regulatory jurisdictions)	
Advisory notices (particularly recall, or field safety corrective action, notices) and alerts	
Approvals in other regulatory jurisdictions	
Trended customer complaints data for the previous three years from all markets where supplied. e.g. Trending of complaint based on category, such as packaging failures.	
Has any device in this application been rejected or the application been withdrawn from any other regulatory authority or body?	☐ Yes ☐ No
If yes, provide the location of the details of the rejection or withdrawal in the supplied supporting data	
Location of details of previous correspondence with the TGA regarding the application	

For MRA EC certificates

Applicable: ☐ Yes ☐ No

Please note

The TGA can only issue EC certificates to manufacturers within Australia. For a manufacturer to be eligible for an EC certificate under the Australia-EU/EFTA MRA the manufacturer must demonstrate that the device is fully (or mostly) manufactured within Australia. Some kinds of devices are excluded from the agreement, or are subject to confidence–building activities.

For further information refer to the ARGMD, and for information about the amended MRA refer to Medical device amendments to the EU-Australia MRA on conformity assessment to come into effect 1 January 2013.

Evidence that the manufacturer has met the applicable European requirements for:	Location of information in supplied supporting documentation
Other European directives or policies those are relevant to the device. Refer to the European Commission's medical device page.	
Information on device where technical or regulatory requirements in the EU differ from the requirements in Australia.	
Requirements of the MDD that are to be included in the manufacturer's quality management system.	
EU Essential Requirements by way of a checklist or gap analysis when compared with the Australian Essential Principles. Refer to: European Medical Device Directive - Essential requirements checklist	
Labelling and instructions for use in compliance with Annex 1, Clause 13 of MDD.	
Provide detailed information if the device(s) contain(s) substances that are carcinogenic, mutagenic, or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC. (Some phthalates must be disclosed on EU labelling).	
A translation procedure (*MEDEV 2.5/5 Rev. 3).*	

ATTACHMENT 2: Substantial change checklist

Please complete this section for:

- Substantial change(s) to quality management system or kinds of device(s) to which the system is applied. (Schedule 3, Part 1, 3, 4 or 5).
- Substantial change(s) to the product design or intended performance. (Schedule 3, Clause 1.6 or Part 2)

Copy this attachment for each kind of medical device as defined by section 41BE of the Act and regulation 1.6 of the Regulations

You are required to provide the information/data location details (i.e. where the document is located within the supplied package) for each section that you select as '***Applicable - Yes***'.

Describe the substantial changes

1.1.1 Change(s) relating to manufacturer, facilities, critical suppliers or processes covered under the scope of the quality management system (QMS)

Applicable: ☐ Yes ☐ No

Substantial change category	Description of change	Location of information in supplied supporting documentation
Details of the changes relating to the scope of a Schedule 3, Part 1, 4 or 5 TGA conformity assessment certificate. E.g. If the change relates to the device category, critical suppliers or manufacturer facilities listed on the certificate.		
Details of changes to Quality Manual. **Note**: At minimum, this must include a reference to documented procedures *ISO 13485, clause 4.2.2*		
Details of changes to manufacturing process. This must include details of the changed manufacturing process, or services provided and the party responsible.		

Substantial change category	Description of change	Location of information in supplied supporting documentation
Details of changes to protocols and reports for the validated processes. *ISO 13485, clause 7.5.6*		
Updated risk management documentation reflecting changes applied for, including current version of risk management report. *ISO 14971:2007, clause 8*		
Details of changes to labels/instructions for use, including representative copies of new labels/instructions for use.		

2.1.1 Change(s) relating to the design (including materials) or intended performance

A substantial change to the design or intended performance of a device covered by a Schedule 3, Clause 1.6 certificate or a Schedule 3, Part 2 certificate that does not result in a new UPI.

Applicable: ☐ Yes ☐ No

Substantial change category	Description of change	Location of information in supplied supporting documentation
Changes relating to the scope of a Schedule 3, Part 1, clause 1.6 or Part 2 TGA conformity assessment certificate e.g. If the change relates to device name, variants, and for Class 4 IHR IVDs devices listed on the certificate.		
Changes to the intended performance.		
Changes to the design (that are not covered above).		
Changes to labels/instructions for use, including representative copies of new labels/instructions for use.		

Substantial change category	Description of change	Location of information in supplied supporting documentation
Updated risk management documentation reflecting changes applied for, including current version of risk management report. *ISO 14971:2007, clause 8*		

3.1.1 For all devices (excluding IVDs) containing medicinal substance(s)

Applicable: ☐ Yes ☐ No

Substantial change category	Description of change	Location of information in supplied supporting documentation
Changes to suppliers This includes change to scope of supplier's facility, addition or deletion of suppliers		
Changes to drug master file (if with TGA) or CEP certificate		
Changes to medicinal substance and/or dose or any other changes		
Up-to-date GMP compliance evidence of each medicinal substance supplier		

4.1.1 For all devices (excluding IVDs) containing material of animal, microbial or recombinant origin

Applicable: ☐ Yes ☐ No

Substantial change category	Description of change	Location of information in supplied supporting documentation
Changes to the intended performance		
Changes to suppliers that provide materials of animal, microbial and recombinant origin This includes change to scope of supplier's facility, addition or deletion of suppliers		
Change to material production process. This includes any changes such as addition/deletion of new steps in the production process.		
Changes to material sources This includes changes to the species, anatomical location etc.		

5.1.1 For all devices (excluding IVDs) containing human blood or human plasma derived materials

Applicable: ☐ Yes ☐ No

Substantial change category	Description of change	Location of information in supplied supporting documentation
Changes to suppliers that provide materials of human blood or human plasma derived		
Changes to PMF (if available)		
Changes to the manufacturing process		

6.1.1 For all sterile devices (excluding IVDs)

Applicable: ☐ Yes ☐ No

Substantial change category	Description of change	Location of information in supplied supporting documentation
Changes to suppliers This includes changes to details of the services/products supplied.		
Changes to sterilisation method/process parameters This includes changes to the equipment.		
Changes to sterile production facilities This includes changes to the clean room, equipment etc.		

ATTACHMENT 3: Recertification checklist

Complete this attachment when applying for recertification of *existing* conformity assessment certificates.

You are required to provide the information/data location details (i.e. where the document is located within the supplied package) for each section that you select as '***Applicable - Yes***'.

For the addition of new UPIs (or new Class 4 IHRs) and substantial changes Section 2.1 and 2.2, as applicable, must be completed.

Quality management system conformity assessment certificates (TGA Schedule 3, Part 1, 3, 4, 5 certificates and/or certificates issued under EU-MRA)

Applicable: ☐ Yes ☐ No

Recertification details	Location of data in supplied supporting documentation
Certificate(s) to be recertified. Provide a copy of the certificate	
Confirm certificate details. Confirm that the manufacturer's name, address, facilities, suppliers, device category and certificate conditions have not changed.	
If available, notified body's most recent full audit report (initial or recertification) with evidence of non-conformity close-out.	
Post-market information • Details of any reportable adverse events, recalls or notices to TGA or other regulatory jurisdictions since certification, including ARTG inclusion numbers. • Trended complaints data for the previous three years from all markets where supplied.	
Latest version of labelling and instructions for use for the device(s) to be recertified.	

Design/Type examination certificates (TGA Schedule 3, Part 1 clause 1.6 and Part 2 certificates)

Applicable: ☐ Yes ☐ No

Recertification details	Location of data in supplied supporting documentation
Certificate(s) to be recertified. Provide a copy of the certificate	
Confirm certificate details Confirm that the manufacturer's name, address, UPIs, and variants, and certificate conditions have not changed.	
Post-market information. • Details of any reportable adverse events, recalls or notices to TGA or other regulatory jurisdictions since certification including device ARTG numbers. • Trended complaints data for the previous three years from all markets where supplied.	
Updated risk management report demonstrating continual compliance with the essential principles, including incorporation of: • experience gained post market • information on existing and new hazards with regard to the 'state of the art' (e.g. standards) and updated clinical data/information • any new regulatory developments	
Latest version of labelling and instructions for use for the device(s) to be recertified.	

For all devices (excluding IVDs) containing medicinal substance(s)

Applicable: ☐ Yes ☐ No

Information	Location of information in supplied supporting documentation
Manufacturing quality Current GMP compliance evidences for each manufacturer that (produces/processes) the medicinal substance.	