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 for medical devices including in-vitro diagnostic devices

Supporting data form

This form should be completed for:

- initial application for new conformity assessment certificates, or
- notification of changes relating to existing certificates

Completing this form

Guidance to completing this form

Grey instructional text will disappear following selection and typing please select and begin typing onto the grey instructional text.

Applicants should refer to the:

- Application instructions: Conformity assessment certification
- Changes affecting TGA-issued conformity assessment certificates
- *Therapeutic Goods Act 1989* (the Act)
- *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) and
- IMDRF Non-In Vitro Diagnostic Device Market Authorization Table of Contents
- IMDRF In Vitro Diagnostic Medical Device Market Authorization Table of Contents
- IMDRF Assembly and Technical Guide for IMDRF Table of Contents Submissions
- Guidelines for reducing assessment fees for ARTG application audits and conformity assessments of medical devices (including IVDs) medical devices
- IVD guidance documents
- Regulation of software based medical devices
- Regulatory framework for personalised medical devices

If this application is for a novel device, the applicant is encouraged to have pre-submission meeting with the TGA by emailing devices@tga.gov.au.

Submitting this form

This form and the associated data should be provided to the TGA only when requested. An electronic TGA e-Business (TBS) application for a conformity assessment certificate must be lodged (and application fee paid) **prior to** submitting this form. A Submission ID is 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 Authorisation Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

or

Courier Delivery

Devices Conformity Assessment Section
Medical Devices Authorisation Branch
Therapeutic Goods Administration
1 Tindal Lane
Canberra Airport ACT 2609

You may also contact our e-Submissions Team (eSubmissions@health.gov.au) to set up a temporary online portal to upload data over 20MB.

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).
  - are translated to English

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

For additional information contact devices@tga.gov.au or IVD specific enquiries IVDs@tga.gov.au.

1. General details

1.1 Application information

Submission ID	e.g. DC-2019-01234-1
Description of the application *Include details of any TGA conformity assessment certificates relevant to this application.*	Click or tap here to enter text.

1.2 Applicant details

Type of Applicant	Choose an item or enter text.
Applicant business name (*Note: This must be same as the client details in the electronic TGA e-Business (TBS) application)*	Applicant Company Name
Applicant's physical address (Client in TBS)	Address Line 1 Address Line 2 SUBURB STATE Postcode Country
Applicant's TGA Client ID	Applicant's TGA Client ID
Applicant's postal address (if applicable)	Address Line 1 Address Line 2 SUBURB STATE Postcode Country
Applicant Contact Details *This person is the primary contact for the purposes of this application and must be*	Contact person's first and last name Telephone Number Mobile Number

authorised agent by the manufacturer. This person should be listed in the TBS database	Email address.

1.3 Contact person details for assessment fee invoicing

TGA Client ID *Note: Applicant or manufacturer's TGA client ID to whom the invoice is to be issued*	TGA Client ID to whom the invoice is to be issued
Full name and position	First and last name, position.
Telephone number	Telephone Number Mobile Number
Email address	Email address

1.4 Request for reduced assessment fee

Assessment fee

For the relevant fees, please refer to the medical devices or IVD 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. The request should be within the cover letter of the application and be made before TGA issues an invoice for assessment fees.

If you wish to request a fee reduction, please outline the reasoning, and include any supporting evidence (such as MDSAP audit report, Notified Body audit report or technical report that is relevant to the application, or references to predicate device approved by the TGA) in the supporting data submission:

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

Location of request letter for abridged assessment	e.g. cover letter / page number

Location of supporting evidence	e.g. MDSAP report - folder name/ filename/ page number)

1.5 Statutory declaration

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

Please access manufacturer's statutory declaration for information, and the applicable forms on this matter.

Information	**Location of information in supplied supporting documentation** **(Specify the location, page number and document file name)**
Completed Certificate for paragraph 41EC (3) (a) of the Act	Specify location (e.g. folder name/ filename/ page number)

2. Application scope

Parts and clauses referred below relate to Schedule 3 of the Regulations.

2.1 Scope of this application

Specify the scope of this application by selecting one or more of the following options:

	Application for new conformity assessment certificate	Application for changes in relation to existing certificate
Conformity assessment certificate		
Schedule 3, Part 1 - Full Quality Assurance	☐	☐
Schedule 3, Part 3 - Verification Procedure (non-sterile only)	☐	☐
Schedule 3, Part 4 - Production Quality Assurance	☐	☐
Schedule 3, Part 5 - Product Quality Assurance (non-sterile)	☐	☐
Design/ type examination certificate		
Schedule 3, Clause 1.6 - Examination of design	☐	☐
Schedule 3, Part 2 – Type Examination	☐	☐

2.2 For changes to existing certificates

Provide certificate numbers:

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):
Change(s) to the product design or intended performance (Schedule 3, Clause 1.6 or Part 2).	List certificate number(s):

2.3 Enter a short description of the application

Click or tap here to enter text.

3. Manufacturer details

Please note

TGA CA certificates are issued in electronic format via email.

Certificates will not be issued unless this information is provided.

3.1 Manufacturer's facility

3.1.1 Manufacturer facility details

Manufacturer's name	Click or tap here to enter text.
Trading name *(if applicable)*	Click or tap here to enter text.
Australian Business number (ABN) / Australian Company number *(if applicable)*	Click or tap here to enter text.
TGA Client ID	Click or tap here to enter text.
Manufacturer's physical address	Click or tap here to enter text.
Manufacturer's postal address *(if different to physical address)*	Click or tap here to enter text.
Facility scope *Specify here the manufacturing/production steps/activities actually performed at this facility (e.g., design, key production steps (specify), packaging, labelling, final release, warehousing and dispatch)*	Click or tap here to enter text.
Website address	Click or tap here to enter text.

3.1.2 Manufacturer's facility contact person details

Full name	Click or tap here to enter text.
Position	Click or tap here to enter text.
Telephone number	Click or tap here to enter text.

Email address	Click or tap here to enter text.

3.2 Additional manufacturing facility (site) details

Please note

If the manufacturer has more than one facility, please complete this section for each additional facility.

All key steps/activities of manufacturing/production, whether undertaken in-house or by critical suppliers, should be accounted for either here or in Section 4, as appropriate.

For a change application, have there been any changes to the manufacturing facilities, as shown on the current certificate?	Not applicable

Copy the table below for each new/change to a manufacturing facility by selecting the table and clicking the + button on the bottom right of the table.

3.2.1 Address and scope

Facility name	Click or tap here to enter text.
Facility physical address	Click or tap here to enter text.
Facility scope *Specify here the manufacturing/production steps/activities actually performed at this facility (e.g. design, key production steps (specify), packaging, labelling, final release, warehousing and dispatch)*	Click or tap here to enter text.

3.3 Current certification details

3.3.1 Special access scheme/ custom-made exemption

Has the product been supplied in Australia under the Special Access Scheme (SAS)?	☐ Yes ☐ No
Has the product been supplied in Australia under the custom-made medical device exemption?	☐ Yes ☐ No

3.3.2 Quality management system certificates held by the manufacturer

Please note

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

Requests for an abridged assessment (Section 1.4) made based on holding other relevant certificates must be accompanied by

- copies of the relevant certificates,
- the most recent full (initial or recertification) audit report,
- any subsequent surveillance reports, and
- if relevant, all Notified Body detailed full technical assessment reports.

The MDSAP or Notified Body audit reports should cover the devices and manufacturing processes relevant to the application. The audit reports must include non-conformities identified during the audits and evidence of acceptance of the corrective actions by the MDSAP Auditing Organisation or Notified Body in relation to these nonconformities.

The Notified Body technical assessment should cover the devices and proposed changes where relevant.

Does the manufacturer hold Quality Management System (QMS) certification (excluding TGA issued certification)? *e.g. QMS certificate issued by an Auditing Organisation under MDSAP or by a Notified Body under the EU MDR/ IVDR along with audit reports.* *Refer to guidance at Use of Market authorisation evidence from comparable overseas regulators/assessment bodies for medical devices.*	☐ Yes ☐ No

Copy the table below if there are additional non-TGA issued QMS certificates held by the manufacturer that are relevant to this application

Information	Detail of information supplied in supporting documentation
QMS Certificate(s) type Include the type of certification (*e.g. Certificate issued under MDSAP or under Regulation (EU) 2017/745, Annex IX, Chapter I and III*)	Click or tap here to enter text.
QMS Certificate(s) identifier	Certificate number/ID

QMS Certificate(s) location	Specify here the location (e.g. document file name/ page number)
MDSAP DUNS Number for each site (if available)	Click or tap here to enter text.
Audit reports *Most recent full (initial/recertification) audit including any subsequent surveillance reports*	Specify here the location (e.g. document file name/ page number)

3.3.3 Design/type examination certificates held by the manufacturer

Does the manufacturer hold Design/Type Examination certification (excluding TGA issued certification)? *e.g., Certificate issued under EU MDR / IVDR along with Notified Body technical report 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.*	☐ Yes ☐ No

Copy and complete this section if there are additional non-TGA issued design certificates held by the manufacturer that are relevant to this application

Information	**Detail of information supplied in supporting documentation**
Design Examination Certificate(s) type Include the type of certification (*e.g. Directive 93/42/EEC on Medical Devices, Annex II Part 4 only*)	Click or tap here to enter text.
Design Examination Certificate(s) identifier	Certificate number/ID
Design Examination Certificate(s) location	Specify here the location (e.g. document file name/ page number)
Regulatory body technical assessment report(s) *(required if abridgement of technical assessment is requested)*	Specify here the location (e.g. document file name/ page number)

3.3.4 For IVD devices only

Does the manufacturer hold ISO 13485:2016 certification?

Note: ISO 13485:2016 certificates will be considered for abridgement of assessment until 26 May 2023. Refer to overseas evidence that can be considered.

☐ Yes ☐ No

Information	**Location of information in supplied supporting documentation** ***(Specify the page number and document file name)***
ISO 13485:2016 Certificates	Click or tap here to enter text.
Audit reports *Most recent full (initial/recertification) audit including any subsequent surveillance reports*	Click or tap here to enter text.

4. Critical supplier details

Critical suppliers include, but are not limited to:

- those entities that supply the organization with finished device, i.e., a device, or accessory to any device, that is suitable for use or capable of functioning, whether or not it is packaged, labelled or sterilized,
- suppliers of products, including services, that impact design outputs that are essential for the proper functioning of the device, and
- suppliers of products and services that require process validation

The following list includes examples of critical suppliers:

- Suppliers of certain types of raw materials, or components, including:
  - medicinal substances, active ingredients
  - material of animal, microbial or recombinant origin
  - off-the-shelf software components
  - feedstock materials for additive manufacturing
  - control kits
  - monoclonal and polyclonal antibodies
  - antigens for Hepatitis C, Human Immunodeficiency Virus (HIV) and Hepatitis B assays
- Suppliers that carry out a key stage of product realisation, including:
  - sterilisation services
  - drug coating process
  - post-processing steps such as applying surface coating, heat treatments and hot isotactic pressing
  - production of reagent red blood cell IVDs
- Suppliers of design and development activities for manufacturers holding, or applying for, a full quality assurance CA certificate.
- The TGA may list some, or all, of the critical suppliers on a Schedule 3, Part 1, 3, 4 or 5 certificates.

Please note

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).

For a change application, have there been any changes to the critical suppliers, as shown on the current certificate?	Not applicable - continue below

Copy the table below for each new (or change to) critical supplier by selecting the table and clicking the + button on the bottom right of the table.

Supplier's name and physical address	Click or tap here to enter text.
Scope *e.g. relevant device, services provided and/or manufacturing stages performed at this site.* *Please indicate the devices impacted by this critical supplier*	Click or tap here to enter text.

5. Non-IVD Device information

For a change application, have there been any changes to the device design or intended purpose?	Choose an item.

Copy the table below for each kind of device by selecting the table and clicking the + button on the bottom right of the table.

Unique Product Identifier (UPI) / Kind of device *For Class III only.* *Kind of device is defined by section 41BE of the Act and regulation 1.6 of the Regulations.*	Click or tap to enter a date.
Device name(s)	Click or tap here to enter text.
GMDN code and term *e.g. 34179 – bio absorbable coronary artery stent, drug-eluting*	Click or tap here to enter text.
ARTG number *(if applicable)*	Click or tap here to enter text.
Device Classification	Select class.
Applicable Australian classification rule *e.g. 3.4(4)(a) – Refer to the Regulations Schedule 2 for medical devices other than IVDs and Schedule 2A for IVD medical devices*	Click or tap here to enter text.
TGA Design Examination Certificate *(if applicable)* *e.g. AU D00XXX*	Click or tap here to enter text.
List of variants *For Class III.* *e.g. diameter and length ranges For further information, refer to the ARGMD.*	Click or tap here to enter text.

Intended purpose *Intended purpose of a kind of medical device, means the purpose for which the manufacturer of the device intends it to be used, as stated in:* *a. the information provided with the device, or* *b. the instructions for use of the device, or* *c. any advertising material applying to the device*	Click or tap here to enter text.
Device description *Include here a description of the device, any components, medicinal substances, animal origin materials, recombinant origin materials, etc incorporated, whether the device is to be used in combination with another device or instrument.* *If applicable, this device description should reflect the description provided on the device IFU.*	Click or tap here to enter text.
Shelf life and storage conditions	Click or tap here to enter text.
Magnetic Resonance (MR) status of implantable devices	☐ N/A, provide rationale ☐ MR Safe ☐ MR Conditional ☐ MR Unsafe
Is the device supplied sterile?	☐ Yes ☐ No
If yes, provide sterilisation method	Choose an item
Use limitations?	☐ Single-use only ☐ Re-usable device ☐ Other:
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
If yes, • Is the software for relevant health professionals or laypersons	☐ Health professionals ☐ laypersons
• classification of software	
• Does the software incorporate artificial intelligence	☐ Yes ☐ No
• Does the software have network connectivity	☐ Yes ☐ No
Is the device a Patient-matched medical device?	☐ Yes ☐ No
Is the device an Adaptable medical device?	☐ Yes ☐ No
Medicinal Substance Device incorporates a medicinal substance that has an action that is ancillary to the device	☐ Yes ☐ No
If yes, • medicinal substance name:	
• medicinal substance concentration / quantity (units) in the device:	
Human blood or plasma Device incorporates an extract from human blood or plasma that has an action that is ancillary to the device	☐ Yes ☐ No
• If yes, indicate extract name / description:	
Animal origin Device incorporates material or substances of animal origin or was manufactured using materials of animal origin:	☐ Yes ☐ No
If yes, • Animal origin substance name and source (e.g. collagen from bovine):	

• Country of origin of animals	
Microbial Origin Device incorporates or was manufactured using material or substances of microbial origin	☐ Yes ☐ No
If yes, • indicate microbial origin substance name	
• indicate whether animal origin materials were being used in the manufacture of microbial origin materials	☐ Yes, animal origin materials are used in the manufacture of the microbial origin materials ☐ No, animal origin materials are not use in the manufacture of the microbial origin materials
Recombinant technology Device incorporates material or substances produced using recombinant technology	☐ Yes ☐ No
If yes, • indicate recombinant origin substance's name:	
• indicate whether animal origin materials were being used in the manufacture of recombinant origin materials	☐ Yes, animal origin materials are used in the manufacture of the recombinant origin materials ☐ No, animal origin materials are not use in the manufacture of the recombinant origin materials

6. IVD medical device information

Copy this section for each kind of device.

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 (not including IHRs) - the UPI *In addition, list all IVDs within an IVD closed system (if relevant) for the UPI*	Click or tap here to enter text.		
For Class 4 IHRs and Class 1, 2 or 3 IVDs - list individual device names to be included as a kind of IVD medical device under the GMDN Collective Term	Click or tap here to enter text.		
TGA Design Examination Certificate *(if applicable)*	Click or tap here to enter text.		
ARTG Number *(if applicable)*	Click or tap here to enter text.		
Classification *Schedule 2A of the Regulations* *See Classification of IVD medical devices*	Class Select class.	Applicable Australian classification rule *e.g. 3.4(4)(a)*	Click or tap here to enter text.
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*	Click or tap here to enter text.		
What is the manufacturer's intended purpose for the kind of IVD medical device?	Click or tap here to enter text.		
Description of the device(s) *Provide sufficient detail to enable differentiation between individual devices within each kind of IVD medical device*	Click or tap here to enter text.		

Does the IVD incorporate an interpretive software component?	☐ Yes ☐ No

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) (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 for medical devices (including IVDs)

ISO 13485 certificates

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

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

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

Information	**Location of information in supplied supporting documentation** *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Manufacturing stages Document containing the overview of manufacturing/production steps/activities for each device, including details of the manufacturing steps, or services provided by the responsible party.	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Quality Manual This should be the latest version of the Quality Manual and 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.*	Click or tap here to enter text.
Purchasing requirements 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 • processes to verify that outsourced services or components meet manufacturer's specifications *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*	Click or tap here to enter text.
Supplier/Quality agreement(s) This should: • be between the manufacturer and supplier/facility, and • define the responsibilities and authorities of each	Click or tap here to enter text.
Validated processes A list of validated processes as per *ISO 13485, clause 7.5.6 and Schedule 3, Part 1.4 and 4.4 of the Regulations* 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 • The frequency of re-validation *Validation of the application of computer software used in production and service provision, and used for the monitoring and measurement of requirements*	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Procedures for design and development *ISO 13485, clause 7.3 and Schedule 3, Part 1.4* This should include: • The procedure for design planning and inputs • The procedures and records for design and development outputs, review, verification, and validation • The procedures and records for design and development transfer; and • The procedures and records for control of design and development changes	Click or tap here to enter text.
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.*	Click or tap here to enter text.
Procedures to notify the TGA (changes) 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. Refer Changes affecting TGA-issued conformity assessment certificates for further guidelines on notifying the TGA. *Schedule 3, Part 1.5(2), 1.6(4), 4.5(2) and 5.5(2) of the Regulations*	Click or tap here to enter text.
Procedures for adverse event reporting Issue and implementation of advisory notices and the notification of adverse events. 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. *ISO 13485, clauses 7.2.3, 8.2.3, 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.* *Schedule 3, Part 1.3(2)(g), Part 4.3(2)(i) or Part 5.3(2)(i) of the Regulations*	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Continued compliance 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*	Click or tap here to enter text.
QMS adequate and efficacious An undertaking (in writing) by the manufacturer to ensure that the quality management system is, at all times, adequate and efficacious. *Schedule 3, Part 1.3(2)(f), Part 4.3(2)(f) or Part 5.3(2)(f) of the Regulations*	Click or tap here to enter text.

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

Does the device hold an interpretative software component: ☐ Yes ☐ No

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

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Risk analysis Results of the risk analysis process conducted in accordance with ISO 14971:2019 (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).	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
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. Please ensure all harms related to adverse events reported from clinical investigations, literature review and clinical experience have been included in the risk analysis.	
Essential principles checklist For checklist template go to essential principles checklist (medical devices)	Click or tap here to enter text.
List of standards applied Details of any conformity assessment standard, medical device standard or applicable guidance documents that have been applied to the kind of medical device.	Click or tap here to enter text.
Clinical Evidence *Ensure evidence provides adequate coverage of the entire intended use including all indications for use. Refer to the Clinical evidence guidelines: Medical devices* *Schedule 3, Part 8 of the Regulations*	
• Clinical investigation data (*if applicable*) Including all pivotal clinical study reports in full	Click or tap here to enter text.
• Clinical literature review (*if applicable*) If this method of evidence is chosen, please ensure it is up to date within 2 years, and 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) – sufficient detail for pivotal publications to enable appropriate synthesis and analysis, and a critical assessment of the data, i.e. study design, methodology, statistics, outcome measures, and length of follow-up, and whether the device (or a predicate or similar marketed device) was used in the study, against the state of the art or standard of care to demonstrate acceptable safety, performance and benefit risk balance for the device	Click or tap here to enter text.
• Full pivotal articles / publication(s)	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
• Clinical experience Include post-market data and other real-world data: • Post-market data from all regulatory jurisdictions where the device (or a predicate or similar marketed device) has been marketed. • Registry data and study design details such as recruitment criteria • Other primary or secondary use of data relating to patient health status or health care delivery. Data source quality and study design should be justified.	Click or tap here to enter text.
• Demonstration of substantial equivalence (if indirect clinical data is submitted) This should: – be provided in the form of a comparison table between the device and the predicate or similar marketed device; and – include all clinical, technical and biological characteristics; and – identify all differences; and – identify and justify the related clinical impact for each difference.	Click or tap here to enter text.
• An up to date (within two years) clinical evaluation report (CER) written by an expert in the relevant field. This is to be 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, and a favourable benefit-risk balance of the device for the intended purpose/use claimed. Please note that the clinical data must be evaluated by competent clinical experts. A competent clinical expert is generally someone with relevant medical qualifications and direct clinical experience in the use of the device or device type in a clinical setting. For a novel, high risk device, the clinical expert is expected to have current or recent clinical experience with the device type (preferably within the past two years).	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
• Curriculum Vitae (CV) Complete and signed (or similar documentation to justify the manufacturer's choice of expert). This should be provided for: – the CER Author; and – each reviewing clinical expert	Click or tap here to enter text.
Technical File *Required only for devices lower than Class III and lower than Class 4 IVDs* Schedule 3, Clause 1.4 This should include, but is not limited to: • Device description and classification • Details about device variants • Design envelope for Patient Matched Medical Devices (PMMDs) • Finished product specifications • Production process controls • Non-clinical bench tests • Pre-clinical data • Essential principles checklist • Stability studies • Justification / gap analysis for standards not applied in full	Click or tap here to enter text.
Software/Firmware **Applicable?** ☐ Yes ☐ No	
• **Description of software** Including build or version number, hardware requirements, network connectivity requirements, cybersecurity measures if applicable, identification of device features controlled by software, the programming language, hardware platform, operating system (if applicable).	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
• **Risk analysis:** Software / Firmware / etc The risk assessment and hazard analysis should take into account device hazards associated with the device's intended use, including both hardware and software hazards.	Click or tap here to enter text.
• **Verification & Validation data (V&V):** Software / Firmware / etc Provide information on software requirement specification, software architecture and design, validation artefacts, defect management process (known defects at release), justification for unwanted bias or data validation/accuracy for training data in the learning algorithm if the software incorporates AI/ML, Test protocols for V&V testing (performance testing protocol, dataset protocol, software integration testing protocol, software unit verification protocol etc.), traceability analysis, human factors/usability considerations, data privacy considerations under Australian privacy and data protection law. Practical operation testing if applicable	Click or tap here to enter text.
• **Artificial Intelligence/Machine Learning (AI/ML)** Objectives of AI/ML Algorithm and model design, Generalisability of the data used for training and testing (synthetic/real data, size of data sets, appropriateness of the data for Australian population)	Click or tap here to enter text.
• **Cybersecurity** Evidence to support cybersecurity controls of the device, including vulnerability and risk analysis, cybersecurity control measures and traceability matrix linking both. Refer to Medical Device cybersecurity guidance for industry	Click or tap here to enter text.
Labelling Essential principle 13, particularly 13.2 and 13.3 This should include: • samples of primary packaging labels including Australian specific labels • samples of secondary packaging labels including Australian specific labels • e-labelling • patient labelling • samples of any additional packaging, printed document or other appropriate media provided in compliance with EP 13.2	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Information about the sponsor Regulation 10.2 • Documentation whereby sponsor's name and address are provided with the device in such a way that a user of the device can readily identify the sponsor	Click or tap here to enter text.
MRI safety information For all implantable medical devices (including stents, AIMDs, leads, orthopaedic implants, heart valves, vascular grafts). This should include: • 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 (e.g.1.5T or 3T), image artefact information, specific absorption rate (SAR) limit	Click or tap here to enter text.
Instructions for use Essential principle 13, particularly 13.4 This should include: samples of the IFU including Australian specific IFU. Ensure all adverse events reported from clinical investigations, literature review and clinical experience have been included in the IFU • User manuals • Technical manuals /operator's manual • Instructional pamphlets / Instructional videos / training materials / other media provided to the users by the manufacturer, distributor or sponsor such as product brochures and promotional materials	Click or tap here to enter text.
Labelling for Schedule 4 substances Additional labelling requirements apply for certain kinds of device that contain a scheduled poison. if the device relates to any of the following, provide labels that meet the poisons standard. Refer to guidelines for labelling. a. injectable tissue reconstructive, augmentation and restoration materials, including collagen, b. medical devices which include anticoagulants, c. artificial tears, d. urinary catheters, or e. intra-articular fluids.	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Patient Implant Card Essential principle 13A, particularly 13A.2 New regulatory requirements for patient implant cards and device leaflets were implemented from 1 December 2018 (See Patient implant cards and information leaflets)	Click or tap here to enter text.
Patient Information Leaflet Essential principle 13A, particularly 13A.3 New regulatory requirements for patient implant cards and device leaflets were implemented from 1 December 2018 (See Patient implant cards and information leaflets).	Click or tap here to enter text.

For Design Examination (Schedule 3, clause 1.6) certificates (not including IVDs)

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.

Applicable? ☐ Yes ☐ No

Information	Location of information in supplied supporting documentation ***(Specify the location within the documents provided. Include details such as the document file name and page number)***
Comprehensive device description and principle of operation This should include, but is not limited to: • A general description of the device, including name, intended purpose(s), intended users and target populations • Product specification including composition, physical characteristics, features and operation modes, input specifications, output and performance characteristics, acceptance criteria, the variants/models and if there are any differences in specification of variants	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
• List of accessories used, and other medical devices or general products used in combination with the device • Design envelope specifications for Patient-matched Medical devices (PMMDs)	
Engineering and human factors (bench testing and performance) A summary table of all verification and validation (V&V) testing performed for each device, including (but not limited to): • the relevant clause from a standard • acceptance criteria • worst-case sample justification • sample size • confidence and reliability levels applied • results • location of the test reports and protocols	Click or tap here to enter text.
Test protocols for Verification and Validation (V&V) testing To demonstrate claimed compliance with relevant device-specific standards	Click or tap here to enter text.
Test reports of V&V testing To demonstrate claimed compliance with relevant device-specific standards	Click or tap here to enter text.
Usability and human factor assessment To demonstrate compliance with IEC 62366 or equivalent standard	Click or tap here to enter text.
Medical Device comparison table If predicate devices (e.g. similar/comparable devices) are used in V&V testing, a comparison table showing the similarities and differences against the predicate or similar marketed device, and a justification on how the tested devices are representative of the subject device	Click or tap here to enter text.
Biological safety **Applicable?** ☐ Yes ☐ No	

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Biological Safety / biocompatibility test reports This should include, but not limited to, • Biological safety evaluation summary report • Full set of individual biological safety/biocompatibility studies conducted according to current relevant standards (e.g. ISO 10993). • If the 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.	Click or tap here to enter text.
Evidence for quality of raw materials This should include, but not limited to, • list of raw materials including packaging materials, • suppliers of raw materials • evidence for quality of raw materials (e.g. Certificate of Analysis, evidence of compliance with European Pharmacopeia (EP), British Pharmacopeia (BP), US Pharmacopeia's (USP) where applicable)	Click or tap here to enter text.
• *In vivo* non-clinical performance and safety animal study data (*if applicable*)	Click or tap here to enter text.
• Drug local release profiles (*if applicable*)	Click or tap here to enter text.
• Resorption profiles (if applicable)	Click or tap here to enter text.
• Endotoxin testing data (if applicable) Refer to Medical Device Standards Order for endotoxin requirements	Click or tap here to enter text.
• Evidence for safety of impurities contained in the final product. The impurities can include, but not limited to: – Sterilisation residuals (if applicable) – Manufacturing process residuals – Leachables from device components and containers or packaging	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Shelf-life validation Description of, and evidence to support the proposed shelf life (including open or in-use shelf life if applicable), and storage conditions. This should include, but is not limited to, evidence for the stability, continued functionality and safety of the device (including chemical, mechanical, physical properties and critical performance characteristics) through its: • specified shelf life • specified storage conditions for real time aging studies	Click or tap here to enter text.
Packaging validation Description of, and evidence to support safety of the packaging materials/configuration. This should include, but is not limited to: • Verification tests of packaging integrity after sterilisation process and transport simulations • Verification tests of packaging integrity after accelerated and real-time aging	Click or tap here to enter text.

For all devices containing medicinal substance(s)

Applicable? ☐ Yes ☐ No

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Manufacturing quality Please refer to Medicinal substances in medical devices | Therapeutic Goods Administration (TGA) With EU certification: A copy of quality management system certificate A copy of design examination certificate Without EU certification: Current GMP compliance evidence for each manufacturer that (produces/processes) the medicinal substance. The evidence shall include the below:	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
a. A valid GMP certificate from an overseas regulatory authority. b. GMP inspection report from the inspection referenced in the GMP certificate issued by an overseas regulatory authority. c. Site master file from the medical substance manufacturer including all appendices/attachments including information about the manufacturer's operations, facilities, and quality management system. d. A declaration from the substance manufacturer outlining any regulatory actions for the facility within the past 3 years. e. Where the medicinal substance is not covered as part of the most recent GMP inspection report (provided in Item b above, please provide a declaration from medicinal substance manufacturer, the medicinal substance is manufactured in the same buildings, under the Pharmaceutical Quality System (PQS), using the same manufacturing process as the substance inspected in the evidence provided. Note: If the substance is not regulated as a medicine in the EU but is a medicine in Australia, you are encouraged to email us at DCAS@health.gov.au.	
For a new chemical entity (NCE) 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	Click or tap here to enter text.
• Non-clinical safety data (e.g. CTD Module 4)	Click or tap here to enter text.
• Confirmation that a Proposed Australian Approved Name Application Form has been submitted.	Click or tap here to enter text.
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) **with no changes**	

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
• Confirmation of the substance quality	Click or tap here to enter text.
• ARTG No. of the product/s containing the same medicinal substance	Click or tap here to enter text.
• TGA DMF Reference No., if available	Click or tap here to enter text.
• 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	Click or tap here to enter text.
• 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	Click or tap here to enter text.
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 a different manufacturer (i.e. a new manufacturer to TGA) or by an existing manufacturer **with changes** in the medicinal substance	
• Quality data (e.g. CTD Module 3, DMF or CEP with supporting data described in Guidance 11 of ARGPM	Click or tap here to enter text.
• TGA Master File (MF) Reference No. if available	Click or tap here to enter text.
• Authorisation letter from the MF manufacturer to allow TGA access to the MF, if there is a MF in the TGA	Click or tap here to enter text.

CEP = Certificate of Suitability to monographs of European Pharmacopoeia; CTD = Common Technical Document; DMF = Drug Master File; GMP = Good Manufacturing Practice; NCE - A chemical, biological or radiopharmaceutical substance that has not previously been included in the ARTG.

For all devices containing material of animal, microbial or recombinant origin

Applicable? ☐ Yes ☐ No

Refer to guidelines on TGA's approach to minimising the risk of exposure to Transmissible Spongiform Encephalopathy (TSE)

Import permit requirements

Medical devices containing materials of animal origin require an import permit from the Department of Agriculture, Fisheries and Forestry. Applicants should apply for an import permit after obtaining the TGA conformity assessment certificate. Information relevant to requirements on import permits and conditions of import can be obtained from Biosecurity Import Conditions system.

Information	**Location of information in supplied supporting documentation** ***(Specify the location within the documents provided. Include details such as the document file name and page number)***
TGA Master File (MF) Reference No (*if available*)	Click or tap here to enter text.
Information on controls related to sourcing/collection/handling. *ISO 22442-2*	Click or tap here to enter text.
Validation of the manufacturing process' capability to clear viruses/ infectious agents/ transmissible pathogenic agents. *ISO 22442-3*	Click or tap here to enter text.
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. *ISO 22442-1*	Click or tap here to enter text.
Confirmation whether animal origin materials were being used in the manufacture of microbial origin. If used, risk assessment that demonstrates the risks have been minimised to an acceptable level in the final product. *ISO 22442-1*	Click or tap here to enter text.

For all devices containing human blood or human plasma derived materials

Applicable? ☐ Yes ☐ No

Refer to guidelines on TGA's approach to minimising the risk of exposure to Transmissible Spongiform Encephalopathy (TSE)

Information	**Location of information in supplied supporting documentation** ***(Specify the location within the documents provided. Include details such as the document file name and page number)***
Information on donor selection and testing of individual donations, minipools and plasma pools (info normally in a PMF).	Click or tap here to enter text.
If PMF (Plasma Master File) is referenced, is a European Medicines Agency PMF certificate referenced.	Click or tap here to enter text.
Validation of the manufacturing process' capacity to clear viruses or pathogenic agents	Click or tap here to enter text.
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.	Click or tap here to enter text.

For all IVDs only

Information	**Location of information in supplied supporting documentation** ***(Specify the location within the documents provided. Include details such as the document file name and page number)***
Comprehensive device description and principle of operation A general description of the device, including name, intended purposes, intended users and target populations Product specification including composition, physical characteristics, features and operation modes, input specifications, output and performance characteristics, acceptance criteria, the variants/models and if there are any differences in specification of variants	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
• List of accessories used, and other medical devices or general products used in combination with the device	
Performance Evaluation: Including (but not limited to): • Specimen stability • Validation of specimens • Measuring range and linearity • Limit of detection • Precision & Trueness • Interfering substances • Traceability of calibrators and controls • Analytical sensitivity and specificity • Clinical sensitivity and specificity • High dose hook effect • Useability	Click or tap here to enter text.

Shelf-life validation and packaging
 	
This evidence must meet ISO 23640 requirements and should include (where applicable):
• Description of the proposed shelf life and storage conditions
• Evidence for the stability, continued functionality and safety of the IVD through its specified shelf life and/or expected lifetime, including:
  − Closed shelf life/Claimed shelf life
  − In use stability
  − Shipping stability
• Packaging materials/configuration
• Packaging validation reports
	Click or tap here to enter text.

A statement indicating whether 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*	Click or tap here to enter text.

For all sterile devices

Applicable? ☐ Yes ☐ No

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
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, frequency of testing and the bioburden test method validation • A report describing the initial validation of the process and information/reports on revalidations carried out • Details of biological indicators, including organism identity, population and resistance to the process, where biological indicators are used for process validation • Method of batch release e.g. biological indicator (BI) release, sterility testing, dosimetric release or parametric release	Click or tap here to enter text.
For products that are manufactured using sterile filtration and aseptic filling or aseptically manufactured **Applicable?** ☐ Yes ☐ No	
• 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	Click or tap here to enter text.
• 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}	Click or tap here to enter text.
• 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	Click or tap here to enter text.

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
• statements of maximum permitted processing times during manufacture (holding, storage and filling times)	Click or tap here to enter text.
• 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	Click or tap here to enter text.
• details of batch release sterility testing	Click or tap here to enter text.
For products that are intended for multi-dose use: **Applicable?** ☐ Yes ☐ No	
• information on antimicrobial preservative efficacy data at the beginning and end of the closed shelf life	Click or tap here to enter text.
• information on microbiological challenge testing/simulated use testing to support the open shelf life (in-use period)	Click or tap here to enter text.
For products with sterilisation residues: *ISO 10993-7* **Applicable?** ☐ Yes ☐ No	
• Sterilisation residue report	Click or tap here to enter text.
• Information on the test article	Click or tap here to enter text.
• Information on the rationale for selection of the representative test article	Click or tap here to enter text.
• Information on the test conditions	Click or tap here to enter text.

For all reusable devices

Applicable? ☐ Yes ☐ No

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Details of cleaning instructions and sterilisation method/process instructions	Click or tap here to enter text.
Validation reports of the cleaning procedure and sterilisation process	Click or tap here to enter text.
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	Click or tap here to enter text.

For all devices – Regulatory history in Australia and other countries

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Post-market surveillance report Where Australian or overseas post-market information is available, please provide up to date (within 6-12 months of application submission) post-market surveillance report on each UPI, including information on the following as a minimum. The information should be separated for Australia and worldwide jurisdictions. The information should be trended for the previous three years from all markets where supplied: • Number of devices supplied • Number and types of complaints • Number and types of reportable adverse events • Analysis of post-market data • Any corrective and preventative actions (CAPAs) • Details of advisory notices (including recall or field safety corrective action, notices and alerts) • Total number of years the device(s) have been supplied for in each jurisdiction	Click or tap here to enter text.

Approvals in other regulatory jurisdictions	Click or tap here to enter text.
Has any device in this application been rejected or the application been withdrawn from any other regulatory authority or body?	☐ Yes ☐ No *provide details below*
If yes, provide the location of the details of the rejection or withdrawal in the supplied supporting data	Click or tap here to enter text.
Location of details of previous correspondence with the TGA regarding the application	Click or tap here to enter text.
Has any device in this application been supplied as a custom-made medical device or listed on ARTG as a component of system or procedure pack.	Click or tap here to enter text.

ATTACHMENT 2: Substantial change checklist

Please complete this section for:

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

Supporting data should be included 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***'. Changes should be accompanied with supporting information which specifically addresses all aspects of changes being proposed. Refer to Changes affecting TGA-issued conformity assessment certificates for further information.

Notification of a substantial change

A TGA issued conformity assessment certificate is subject to automatic conditions imposed under section 41EJ of the Act. One of these conditions requires that the person in respect of whom the certificate is issued (i.e. the manufacturer) will notify in writing the Secretary of the Department of Health and Aged Care of any plan for substantial changes to:

a. quality management systems; or

b. the product range covered by those systems; or

c. the product design of kinds of medical devices

in respect of which the certificate is issued.

Short description of change

Information	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Notification to the Secretary for a substantial change (section 41EJ(3) of the Act).	Click or tap here to enter text.

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

Applicable? ☐ Yes ☐ No

Substantial change category	Applicable changes?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Quality Manual This must reflect the most recent version, include a reference to documented procedures and should reflect the proposed changes. *ISO 13485, clause 4.2.2 and Schedule 3, Part 1.4 and 4.4 of the Regulations.*	☐ Yes ☐ No	Click or tap here to enter text.
Purchasing requirements 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 • processes to verify that outsourced services or components meet manufacturer's specifications *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*	☐ Yes ☐ No	Click or tap here to enter text.
Supplier/Quality agreement(s) This should:	☐ Yes ☐ No	Click or tap here to enter text.

Substantial change category	Applicable changes?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
• be between the manufacturer and supplier / facility, and • define the responsibilities and authorities of each		
Manufacturing processes This must include details of the changes to the manufacturing process, or services provided and / or the party responsible.	☐ Yes ☐ No	Click or tap here to enter text.
Validated processes Details of changes to protocols and reports for the validated processes. *ISO 13485, clause 7.5.6*	☐ Yes ☐ No	Click or tap here to enter text.
Sterilisation processes Validation protocols and reports for the sterile barrier systems and packaging systems or justification why revalidation was not necessary. *ISO 13485, clause 7.5.5-7.5.7 and Schedule 3, Part 1.4 and 4.4 of the Regulations*	☐ Yes ☐ No	Click or tap here to enter text.
Stability Stability protocols and reports on the product and primary packaging system, or justification why stability has not been impacted by the change. *ISO 13485, clause 7.5.5-7.5.7 and Schedule 3, Part 1.4 and 4.4 of the Regulations*	☐ Yes ☐ No	Click or tap here to enter text.
Design and development Procedures and reports for manufacturer's review and control over changes *ISO 13485, clause 7.3 and Schedule 3, Part 1.4*	☐ Yes ☐ No	Click or tap here to enter text.
Information provided with the device Documentation relating to changes in the labelling, instructions for use (IFU), patient information leaflet (PIL), patient implant card (PIC), or other documentation provided with the device. Representative copies of each	☐ Yes ☐ No	Click or tap here to enter text.

Substantial change category	Applicable changes?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Risk Management Documentation Updated risk management documentation reflecting the proposed changes as detailed above. Including current version of risk management report. *ISO 14971:2019, clause 8*	☐ Yes ☐ No	Click or tap here to enter text.
Specific changes to the TGA Certificate Changes relating to the scope of a Schedule 3, Part 1, 4 or 5 TGA conformity assessment certificate including, but not limited to, changes to/removal of a: • device category • critical supplier • manufacturing facility as listed on the certificate.	☐ Yes ☐ No	Click or tap here to enter text.

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

Applicable? ☐ Yes ☐ No

Substantial change category	Applicable?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Device description, intended purpose and/or principle of operation Changes to the description of the device, device name, unique product identifier (UPI), intended purpose, intended performance, indications, intended users and target users / populations	☐ Yes ☐ No	Click or tap here to enter text.
Product specification Changes to the product specifications, including but not limited to: • composition	☐ Yes ☐ No	Click or tap here to enter text.

Substantial change category	Applicable?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
• physical characteristics • features and operation modes • input specifications • output and performance characteristics • acceptance criteria • Shelf-life		
Accessories/devices/general products used in combination Changes to the accessories, other medical devices or general products used in combination with the device	☐ Yes ☐ No	Click or tap here to enter text.
Variants/models Changes to the variants / models or changes to the specification of these variants / models	☐ Yes ☐ No	Click or tap here to enter text.
For Patient-matched medical devices (PMMDs) Changes to design envelope specification	☐ Yes ☐ No	Click or tap here to enter text.
Magnetic Resonance (MR) status Changes in/to the MR safety data, including but not limited to: • Changes to the MR status (such as MR safe, MR conditional and MR unsafe) • Updated documentation in relation to MR instructions (IFU, PIL and user manual)	☐ Yes ☐ No	Click or tap here to enter text.
Verification/Validation (V&V) Changes to V&V including, but not limited to: • Updated verification and validation testing, • justification for any tests which were not performed after the change(s) • a summary table of all verification and validation testing performed for each device • the relevant clause from a standard • acceptance criteria • worst-case sample justification • sample size • confidence and reliability levels applied results • the test report and protocol	☐ Yes ☐ No	Click or tap here to enter text.

Substantial change category	Applicable?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Information provided with the device Changes in the labelling, instructions for use (IFU), patient information leaflet (PIL), patient implant card (PIC), or other documentation provided with the device. Provide representative copies of each including red-line and clean copies.	☐ Yes ☐ No	Click or tap here to enter text.
Design changes (not covered above) Description of changes that are not covered in the sections above.	☐ Yes ☐ No	Click or tap here to enter text.
Risk Management Documentation Updated risk management documentation reflecting the proposed changes as detailed above. Including current version of risk management report. *ISO 14971:2007, clause 8*	☐ Yes ☐ No	Click or tap here to enter text.
Risk Management Report The current version of risk management report *ISO 14971:2019, clause 8*	☐ Yes ☐ No	Click or tap here to enter text.
Specific changes to the TGA Certificate 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 or variants listed on the certificate or if a device is to be removed.	☐ Yes ☐ No	Click or tap here to enter text.

Changes relating to software

Substantial change category	Applicable changes?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Description of change	☐ Yes ☐ No	Click or tap here to enter text.
Risk analysis: Software/Firmware, etc.	☐ Yes ☐ No	Click or tap here to enter text.
V&V: Software/Firmware, etc. Provide information on software requirement specification, software architecture and design, validation artefacts, defect management process (known defects at release), justification for unwanted bias or data validation/accuracy for training data in the learning algorithm if the software incorporates AI/ML, test protocols for V&V testing (performance testing protocol, dataset protocol, software integration testing protocol, software unit verification protocol etc.), traceability analysis, human factors/usability considerations, data privacy considerations under Australian privacy and data protection law. Practical operation testing if applicable.	☐ Yes ☐ No	Click or tap here to enter text.
Artificial Intelligence/Machine Learning (AI/ML) Objectives of AI/ML Algorithm and model design, Generalisability of the data used for training and testing (synthetic/real data, size of data sets, appropriateness of the data for Australian population)	☐ Yes ☐ No	Click or tap here to enter text.
Cybersecurity Evidence to support cybersecurity controls of the device, including vulnerability and risk analysis, cybersecurity control measures and traceability matrix linking both. Refer to Medical Device cybersecurity guidance for industry	☐ Yes ☐ No	Click or tap here to enter text.

Changes for all devices containing medicinal substance(s)

Applicable? ☐ Yes ☐ No

Substantial change category	Applicable?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Medicinal substance suppliers Changes to the medicinal substance supplier including, but not limited to: change to scope of supplier's facility addition or deletion of suppliers	☐ Yes ☐ No	Click or tap here to enter text.
Drug Master File (DMF) Changes to drug master file (*TGA*) or CEP certificate.	☐ Yes ☐ No	
Medicinal substance Changes to medicinal substance, dose or any other changes, including changes to the medicinal substance production process.	☐ Yes ☐ No	Click or tap here to enter text.
GMP compliance evidence Up to date GMP compliance evidence of each medicinal substance supplier	☐ Yes ☐ No	Click or tap here to enter text.

Changes for all devices containing material of animal, microbial or recombinant origin

Applicable? ☐ Yes ☐ No

Substantial change category	Applicable?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Material supplier Changes to suppliers that provide materials of animal, microbial and recombinant origin including, but not limited to: • change to scope of supplier's facility • addition or deletion of suppliers	☐ Yes ☐ No	Click or tap here to enter text.
Production processes This includes any changes such as addition / deletion of new steps in the production process, materials specifications.	☐ Yes ☐ No	Click or tap here to enter text.
Material source Including, but not limited to: • changes to the species • anatomical location • country of origin, etc.	☐ Yes ☐ No	Click or tap here to enter text.

Changes for all devices containing human blood or human plasma derived materials

Applicable? ☐ Yes ☐ No

Substantial change category	Applicable?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Material Supplier Changes to suppliers that provide materials of human blood or human plasma derived including, but not limited to: change to scope of supplier's facility addition or deletion of suppliers	☐ Yes ☐ No	Click or tap here to enter text.
Plasma Master File (PMF) Changes to PMF *(if available)*	☐ Yes ☐ No	Click or tap here to enter text.

Substantial change category	Applicable?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Production processes This includes any changes such as addition / deletion of new steps in the production process, materials specifications	☐ Yes ☐ No	Click or tap here to enter text.

Changes for all sterile devices

Applicable? ☐ Yes ☐ No

Substantial change category	Applicable?	Location of information in supplied supporting documentation *(Specify the location within the documents provided. Include details such as the document file name and page number)*
Sterilisation Suppliers Changes to details of the services / products supplied, etc	☐ Yes ☐ No	Click or tap here to enter text.
Sterilisation method / process parameters Changes to the sterilisation equipment, etc	☐ Yes ☐ No	Click or tap here to enter text.
Sterile production facilities Changes to the clean room, equipment etc	☐ Yes ☐ No	Click or tap here to enter text.