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 <http://www.tga.gov.au/about/tga-information-to.htm>.

Attachment 1: New certificate checklist

You are required to complete this attachment for:

- New conformity assessment certificate(s) (Schedule 3, Parts 1, 3, 4 or 5 only).
- New Unique Product Identifier(s)/Devices (Schedule 3, Clause 1.6 (Design examination) or Part 2 (type examination) only).

You are required to provide the data location details (i.e. where the document is located within the supplied data package) when a section is checked as 'Applicable Y þ '.

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 Quality Management System design and development records showing conformity to 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: 2003, Clause 7.3) and should also include the elements listed in the sections below where relevant to the type of product.	

Quality Management System documentation **Applicable** ☐ **Y** ☐ **N**

Manufacturers must be able to demonstrate that a scheduled program of internal audit and management review in accordance with ISO13485:2003-Clauses 8.2.2 and 5.6, has been defined, and undertaken, prior to an audit. These processes must consider whether the manufacturer has

implemented and complied with ISO13485:2003 and the regulatory requirements of target markets (e.g., Australia, Canada and the European Union.)

If an audit of the manufacturer's QMS is required during this application, the Office of Manufacturing Quality (OMQ) will contact the manufacturer prior to the audit and request relevant QMS documentation for review.

Information	Location of information in supplied supporting documentation
Overview of manufacturing stages for each device (detailing manufacturing steps, or service provided, and the responsible party-i.e., named critical supplier or manufacturer's facility).	
Requirements related to the product (ISO13485, Clause 7.2.1)	
Latest version of the Quality Manual (ISO 13485, clause 4.2.2) Note: At minimum, this must include a reference to documented procedures.	
A description of how purchasing requirements are fulfilled for the suppliers identified at section 4 of this form. (ISO 13485, clause 7.4.1, 7.4.2 and 7.4.3)	
List of processes where the resulting output cannot be verified by subsequent monitoring or measurement and the status of their validation (ISO 13485, clause 7.5.2.1)	
For each process validation considered critical to the safety and effectiveness of the device: · 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. State the frequency of re-validation	
Procedures for a post-market monitoring system (ISO 13485, clauses 8.2.1; *Therapeutic Goods (Medical Devices) Regulations 2002 (Regulations)*- Schedule 3, Part 1 1.4(3) , Part 4 4.4(3) or Part 5 5.4(3)).	

Information	Location of information in supplied supporting documentation
Procedure for the issue and implementation of advisory notices and the notification of adverse events (ISO 13485, clauses 7.2.3, 8.5.1; *Regulations*-Schedule 3, Part 1 1.4(3), Part 4 4.4(3) or Part 5 5.4(3) and regulation 5.7-Uniform Recall Procedure).	
Procedures for a corrective and preventive action system (ISO 13485, clauses 8.5.2, 8.5.3; *Regulations*-Schedule 3, Part 1 1.4(3), Part 4 4.4(3) or Part 5 5.4(3) and regulation 5.7).	
Procedures for records control (ISO 13485, clauses 4.2.4; *Regulations*-Part 8 regulation 8.1)	
An undertaking (in writing) by the manufacturer to continue to comply with the requirements of the quality management system after assessment.* (*Regulations*-Schedule 3, Part 1.3(2)(e), Part 4.3(2)(e) or Part 5.3(2)(e)).	
An undertaking (in writing) by the manufacturer to ensure that the quality management system is at all times adequate and efficacious.* (*Regulations*-Schedule 3, Part 1.3(2)(f), Part 4.3(2)(f) or Part 5.3(2)(f)).	
An undertaking (in writing) by the manufacturer to notify the Secretary, 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.* (*Regulations*-Schedule 3, Part 1.3(2)(g), Part 4.3(2)(i) or Part 5.3(2)(i)).	

For each kind of device

Copy this table for each kind of medical device as defined by the *Therapeutic Goods Act 1989*, Section 41BE.

Information	Location of information in supplied supporting documentation
Results of the risk analysis process and how the risks identified have been controlled to an acceptable level. This typically would include the final risk management report, any associated risk analysis documentation, and details on how the risk acceptability criteria have been determined. (ISO 14971:2007) Results of the risk analysis process 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, and details on how the risk acceptability criteria have been determined (i.e., by reference to clinical performance requirements according to the attended purpose of the device). Please note that reference to requirements specified in a technical standard would not normally be sufficient in of itself for demonstrating the clinical justification of risk acceptability. (ISO 14971: 2007)	
List of standards a. List the standards that have been complied with in full or in part in the design and manufacture of the device. b. A discussion of the standards considered for the device and support for their selection or omission. c. At a minimum, the above should include the standard organisation, standard number, standard title, year/version, and if full or partial compliance claimed. d. If partial compliance, a list of the sections of the standard that: i. Are not applicable to the device, and/or ii. have been adapted, and/or iii. were deviated from for other reasons – discussion to accompany	

Information	Location of information in supplied supporting documentation
Clinical evidence (EP14, Regulation 3.11, Schedule 3, Part 8). This should include the following: a. Clinical trial data (where applicable). b. Clinical literature review (where applicable). c. A clinical evaluation report written by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the device. d. A complete curriculum vitae, or similar documentation, to justify the manufacturer's choice of the clinical expert.	
Labelling and instructions for use	
Advertising material	

For all devices (excluding IVDs) containing medicinal substance(s) **Applicable** ☐ **Y** ☐ **N**

Information	Location of information in supplied supporting documentation
Details of whether the medicinal substance(s) have been previously used in therapeutic goods supplied in Australia (i.e., ARTG entry, detail ARTG inclusion)	
Details of whether the Drug Master File(s) have been submitted to the TGA (i.e., include a letter from the drug supplier that gives the TGA authorisation to use the Drug Master File for the purpose of assessing your application)	
Details of quality and safety data regarding medicinal requirements for new chemical entities (e.g., chemical and pharmaceutical data, toxicology, etc-for further guidance, please see ARGMD Part 2 <http://www.tga.gov.au/industry/devices-argmd.htm>)	
Details of the TGA GMP clearance for the medicinal-substance manufacturer(s)	

For all devices (excluding IVDs) containing material of animal, microbial or recombinant origin **Applicable ☐ Y ☐ N**

Information	Location of information in supplied supporting documentation
Details of quality management system records of the assessment and control of the subcontractors that source the manufacturer with materials	
Details of evidence to demonstrate compliance with Conformity Assessment Standard Order No 2 for devices containing materials of animal origin	
Details of information on source and manufacturing process of materials	
Details of evidence to minimise risks for transmission of pathogens	

For all sterile devices (excluding IVDs) **Applicable ☐ Y ☐ N**

Information	**Location of information in supplied supporting documentation**
Sterilisation validation reports (including method/process)	
Sterilisation residue report(s), where applicable	
Details of information on source and manufacturing process of materials	
Details of evidence to minimise risks for transmission of pathogens	

For all reusable devices (excluding IVDs) **Applicable ☐ Y ☐ N**

Information	**Location of information in supplied supporting documentation**
Evidence of cleaning and sterilisation method/process instructions	
Evidence of cleaning and sterilisation validation reports	

Information	Location of information in supplied supporting documentation
Evidence of information to be provided by the manufacturer for the processing of re-sterilisable medical devices (EN ISO 17664 or equivalent or better)	

For all devices incorporating software **Applicable ☐ Y ☐ N**

Evidence that the manufacturer has met the applicable EPs by, for example, demonstrating compliance with:	Location of data in supplied supporting documentation
IEC 62304 - Software lifecycle process (or equivalent or better)	
IEC 62366 - Useablity engineering (or equivalent or better)	

For electrical and electronic devices **Applicable ☐ Y ☐ N**

Evidence that the manufacturer has met the applicable EPs by, for example, demonstrating compliance with:	Location of data in supplied supporting documentation
IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (or equivalent or better)	
IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (or equivalent or better	

Regulatory history in Australia and other countries **Applicable ☐ Y ☐ N**

A concise summary of post-market performance data, including details of:	Location of data in supplied supporting documentation
Adverse events (GHTF / EU / TGA reportable)	
Advisory notices (particularly recall, or field safety corrective action, notices) and alerts	
Summary of clinical trial data	

A concise summary of post-market performance data, including details of:	Location of data in supplied supporting documentation
Summary of other clinical data (e.g., customer surveys)	
Approvals in other regulatory jurisdictions	

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 in the supplied supporting data	
Location of details of previous correspondence with the TGA regarding the application	

For MRA CE certificates **Applicable** ☐ **Y** ☐ **N**

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

For further information refer to the *Australian Regulatory Guidelines for Medical Devices* <http://www.tga.gov.au/industry/devices-argmd.htm>, and for information about the amended MRA refer to the TGA website <http://www.tga.gov.au/about/international-eu-mra-amendments.htm>.

Evidence that the manufacturer has met the applicable European requirements for:	Location of information in supplied supporting documentation
Other European directives or policies that are relevant to the device. Refer to <http://ec.europa.eu/health/medical-devices/other-related-policies/index_en.htm>.	
Devices where technical or regulatory requirements in the EU differ from the requirements in Australia.	

Evidence that the manufacturer has met the applicable European requirements for:	Location of information in supplied supporting documentation
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. <http://www.tga.gov.au/industry/devices-forms-ecmra-ep-checklist.htm>.	
Labelling and instructions for use in compliance with Annex 1, Clause 13 of MDD.	
Provide details 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).	