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 2: Substantial change checklist

Please complete this section for:

- Substantial changes to the QMS for existing conformity assessment certificate(s) (Schedule 3, part 1, 3,4 or 5 only)
- Substantial changes to the design of an existing Unique product Identifier / Device (Schedule 3, Clause 1.6 (Design Examination) or part 2 (type Examination) only)

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

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 '.

Describe the provided substantial changes

Description: Description of each change (if applicable)

Location: Location of data in supplied supporting documentation

Description of substantial changes provided		
Change(s) relating to manufacturer, supplier, or Quality Management System (QMS) (e.g., if the change affects the manufacturer details, the manufacturer facilities, the suppliers or subcontractors, or the quality management system)	**Applicable**	☐ Y ☐ N
	Description	
	Location	

Description of substantial changes provided		
Change(s) relating to the scope of a TGA conformity assessment certificate(s) Schedule 3, Part 1, 4 or 5 (e.g., if the intention is to extend the scope of a Schedule 3, Part 1, 4, or 5 certificate to add new GMDN codes, or for the introduction of substantial changes to products under a GMDN category)	**Applicable**	☐ Y ☐ N
	Description	
	Location	
Change(s) relating to the design, material, product or intended purpose (e.g., if the change affects the design, indications, etc. of a UPI (unique product) covered by a Schedule 3, Clause 1.6 or a Schedule 3, Part 2 certificate but it does not result in a new UPI).	**Applicable**	☐ Y ☐ N
	Description	
	Location	

Details of previous correspondence with the TGA regarding the application:

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

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 'Y þ '.

Information	Substantial change	Location of information in supplied supporting documentation
Details of changes to Quality Manual (ISO 13485:2003, clause 4.2.2) Note: At minimum, this must include a reference to documented procedures	☐ Yes ☐ No	
Details of changes to product requirements (specifications) for the product	☐ Yes ☐ No	
Details of changes to manufacturing stages (detailing manufacturing steps or service provided and party responsibility-i.e., named critical supplier or manufacturer's facility)	☐ Yes ☐ No	
Details of changes to processes where the resulting output cannot be verified by subsequent monitoring or measurement and the status of their validation (ISO 13485:2003, clause 7.5.2.1)	☐ Yes ☐ No	
Details of changes to essential principles checklist supplied <http://www.tga.gov.au/industry/devices-forms-essential-principles-checklist.htm>. Note: Please include a separate Essential Requirements checklist (as per the MDD) if applying for CE Certification.	☐ Yes ☐ No	
Details of changes to review of risk management file for currency and relevance, including current copy of risk management report (ISO 14971:2007, clause 8)	☐ Yes ☐ No	
Details of changes to labelling and/or instructions for use	☐ Yes ☐ No	
Details of changes to advertising material	☐ Yes ☐ No	

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

Information	Substantial change	Location of information in supplied supporting documentation
Details of changes to suppliers (including which suppliers provide which services or materials for which products)	☐ Yes ☐ No	
Details of changes to production process	☐ Yes ☐ No	
Details of changes to production facilities (e.g. new equipment)	☐ Yes ☐ No	
Details of changes to drug master file	☐ Yes ☐ No	
Details of up-to-date GMP clearance status of supplier(s)	☐ Yes ☐ No	
Details of changes to drug substance and/or dose	☐ Yes ☐ No	

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

Information	**Substantial change**	**Location of information in supplied supporting documentation**
Details of changes to suppliers that provide materials of animal, microbial and recombinant origin	☐ Yes ☐ No	
Details of significant change to production process	☐ Yes ☐ No	
Details of changes to material species origin	☐ Yes ☐ No	

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

Information	**Substantial change**	**Location of information in supplied supporting documentation**
Details of changes to suppliers (including which suppliers provide which services for which products)	☐ Yes ☐ No	
Details of changes to sterilisation method/process	☐ Yes ☐ No	

Information	Substantial change	Location of information in supplied supporting documentation
Details of changes to sterile production facilities (e.g. new clean room, new equipment)	☐ Yes ☐ No	

For each device **Applicable ☐ Y ☐ N**

Information	Substantial change	Location of information in supplied supporting documentation
Details of concise summary of all design and production changes	☐ Yes ☐ No	
Detailed description of any safety related design or production changes (e.g. in response to adverse event or recall)	☐ Yes ☐ No	
Details of any changes to the intended purpose of the device	☐ Yes ☐ No	

For each device **Applicable ☐ Y ☐ N**

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)	

Information	Location of information in supplied supporting documentation
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	
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	