Devices Sponsor Information Day

UNDERSTANDING THE TGA’S REGULATORY FRAMEWORK

SUPPORTING ORGANISATIONS —

www.sponsor-day.org
Medical Devices
Manufacturer’s evidence and applications for ARTG inclusion

Session Chair —
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General Manager, Brandwood Biomedical

Speakers / Panelists —
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Therapeutic Goods Administration

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Regulatory Affairs Manager, Device Technologies Australia
Medical Devices
Manufacturer Evidence and applications for ARTG inclusion

Neetal Paranjape
Application and Verification Section
Medical Devices Branch
Devices Sponsor Information Day

15 October 2015
### Purpose

<table>
<thead>
<tr>
<th>Facilitate better understanding of the regulatory requirements for medical devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARTG inclusion – explain the process and give some examples</td>
</tr>
</tbody>
</table>
What is a medical device?

- Used for human beings
- Intended purpose
  - Diagnose, prevent, monitor, treat or alleviate disease or compensate for injury or disability
  - Investigation, replacement or modification of anatomy or physiological processes
  - Control conception
  - Accessory to a medical device as described above
- Is to be ascertained from the information provided on or in any one or more of the following:
  - Labelling
  - Instructions for use
  - Any manufacturer’s advertising material relating to the product
  - Technical documentation

*Therapeutic Goods Act 1989, section 41BD*
Examples
ARTG inclusion

- Any medical device must be included in ARTG
- Except:
  - Exempt devices (e.g. custom-made medical devices)
- Sponsor is responsible for ARTG inclusion
Before you start

• TGA Business Services (TBS)
  – Register and get your Client ID
Important

Classification based on the intended purpose

Conformity assessment procedures

Essential principles for safety and performance

Post-market monitoring
Process for ARTG inclusion

Basics - process through TGA

1. Sponsor
   - Manufacturer Evidence (except for Class I IVD/Class I)
   - Submit application for Class I IVD or Class I (not IVD)

2. Pay application fee
3. Application effective?
   - Yes: Audit?
     - Yes: TGA requires information & audit fee (if applicable)
     - No: Decision to include (ARTG entry)
   - No: Notification of the reason why

4. Decision
   - Yes: Notification [TBS email]
   - No: Notification of the reason why

5. End
Manufacturer evidence

- Manufacturer must apply **appropriate conformity assessment procedure to the device** (quality management system and control over the design of the device)
- Sponsor must lodge the manufacturer’s certification of the conformity assessment with the TGA
  - Except for Class I medical devices (no measuring function and/or not supplied sterile)

Acceptable certificates:

- TGA conformity assessment certificate
- EC Certificate issued under MDD 93/42/EEC or AIMDD 90/385/EEC
- MRA certificates issued by EU Notified Body (with certain exceptions)
- Declarations of conformity made under Clause 7.5 of Schedule 3 (systems or procedure packs)
Sponsor – check before submitting application for Manufacturer Evidence

- Manufacturer’s name is the same as the name on the device / device label
- Address includes the street address and country of origin
- Certificate is appropriate for the device (Directive, Annex and the scope)
- Notified Body – accreditation
- Certificate number and its expiry date
TGA – what will be considered?

- Is information on the Certificate provided in English?
- Is Certificate acceptable?
  - do not submit ISO certificates or FDA certificates or European Declaration of conformity
- Is Notified Body accredited for the type of medical device?
- Do we have concerns about any information provided on the Certificate?
- Is Certificate current (not expired)?
- Have all pages been provided (e.g. Attachments)?
Manufacturer Evidence

✓ ACCEPTED

- What does it mean?

Go to the next step - lodging application for ARTG inclusion
Application for ARTG inclusion

• Must be made for a kind of device and

• Must be effective
  - Made in accordance with a form and manner approved (via TBS)
  - Application fee is paid
  - For the devices that must have TGA conformity assessment certificate – such certificate is in force
  - Must not contain information that is false or misleading in a material particular

Therapeutic Goods Act 1989, sections 41FC and 41EA and Therapeutic Goods (Medical Devices) Regulations 2002, regulation 4.1
Matters certified must be correct

- medical device
- intended purpose
- correctly classified
- essential principles and availability of information to substantiate compliance
- application of conformity assessment procedure and availability of information
- requirements (if any) relating to advertising
- prohibited imports
- excluded purposes (for IVD only)
- information in or with the application is complete and correct

*Therapeutic Goods Act 1989, section 41FD*
Common questions

- Kind of device
- Intended purpose
- Classification
- Conformity assessment procedure
- GMDN code
Kind of device

A medical device is taken to be of the same kind as another medical device if they have the same:

- Sponsor
- Manufacturer
- Device nomenclature system code (GMDN)
- Classification
- Unique product identifier (UPI) (for Class III devices and active implantable medical devices)

Therapeutic Goods Act 1989, section 41BE and Therapeutic Goods (Medical Devices) Regulations 2002, regulations 1.6 and 1.7
Examples of the kinds of devices

• Hypodermic needles – the same sponsor, manufacturer, Class and GMDN Code
  ✓ These devices are of the same kind
• Hypodermic needles – the same manufacturer, Class and GMDN Code, however different sponsor
  ✗ These devices are not of the same kind
Intended purpose of a kind of device

• Means the purpose for which the manufacturer of the device intends it to be used, as stated in the information provided with the device (labelling, instructions for use, advertising material and technical documentation)

• Intended purpose stated in the application must be consistent with the purpose for which the manufacturer intends the devices of the kind to be used
  - specific versus general
  - 500 characters only (in the application)
Medical devices are classified having regard to the intended purpose of the device

<table>
<thead>
<tr>
<th>Class I</th>
<th>Class Is and Class Im</th>
<th>Class IIA</th>
<th>Class IIB</th>
<th>Class III and AIMD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The lowest level</td>
<td></td>
<td></td>
<td></td>
<td>The highest level</td>
</tr>
</tbody>
</table>

*Therapeutic Goods (Medical Devices) Regulations 2002, Part 3 Division 3.1*
Classification (Schedule 2)

Part 1 – Interpretation
(Transient, short-term and long-term use)

Part 2 – Rules for non-invasive medical devices

Part 3 – Rules for invasive and implantable medical devices

Part 4 – Special rules for active medical devices

Part 5 – Special rules for particular kinds of medical devices
Common questions

- Interpretation of:
  - invasive and surgically invasive
  - active medical device
  - potentially hazardous
  - duration of use
  - vital physiological parameters
# Classification examples

<table>
<thead>
<tr>
<th>Classification</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Wound drainage collection bottle</td>
</tr>
<tr>
<td>Class I sterile</td>
<td>Sterile dressings</td>
</tr>
<tr>
<td>Class I measuring</td>
<td>Weighing scale</td>
</tr>
<tr>
<td>Class IIa</td>
<td>IV tubing</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Electrosurgical electrode</td>
</tr>
<tr>
<td>Class III</td>
<td>Cardiovascular catheters</td>
</tr>
<tr>
<td>AIMD</td>
<td>Implantable pacemakers</td>
</tr>
</tbody>
</table>
Conformity assessment procedure

- Minimum conformity assessment procedures for different Classes of devices

- Sufficient information to demonstrate application of the appropriate conformity assessment procedures to the kind of device
  - Certificate
  - Declaration of conformity

Part 3 Division 3.2 and Schedule 3, Therapeutic Goods (Medical Devices) Regulations 2002
### Conformity assessment procedures

<table>
<thead>
<tr>
<th>Medical device (non-IVD) – Class*</th>
<th>Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002</th>
<th>EC Certificate issued under MDD 93/42/EEC (Declaration must be made in accordance with Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002)</th>
<th>Provided under TG (MD) Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Declaration of Conformity - Part 6</td>
<td>N/A</td>
<td>Regulation 3.9(1)</td>
</tr>
<tr>
<td>Class Is</td>
<td>Declaration of Conformity - Part 6 ** plus:** CAC** Production Quality Assurance - Part 4</td>
<td>• Annex II.3 OR&lt;br&gt;• Annex V (‘sterility aspects’ or equivalent wording)</td>
<td>Regulation 3.9(2)</td>
</tr>
<tr>
<td>Class Im</td>
<td>Declaration of Conformity - Part 6 ** plus CAC issued under either:**&lt;br&gt;• Verification - Part 3 or&lt;br&gt;• Production Quality Assurance - Part 4 or&lt;br&gt;• Product Quality Assurance – Part 5</td>
<td>• Annex II.3 or&lt;br&gt;• Annex IV (specific batches are included on the certificate) or&lt;br&gt;• Annex V or&lt;br&gt;• Annex VI (‘metrology aspects’ or equivalent wording)</td>
<td>Regulation 3.9(3)</td>
</tr>
<tr>
<td>Class IIa</td>
<td>CAC Full Quality Assurance - Part 1 (excluding clause 1.6 Design Examination) or Declaration of Conformity - Part 6 ** plus CAC issued under either:**&lt;br&gt;• Verification - Part 3 (for non-sterile devices) or&lt;br&gt;• Production Quality Assurance - Part 4 or&lt;br&gt;• Product Quality Assurance – Part 5 (for non-sterile devices)</td>
<td>• Annex II.3 or&lt;br&gt;• Annex IV (for non-sterile devices where specific batches are included on the certificate) or&lt;br&gt;• Annex V or&lt;br&gt;• Annex VI (for non-sterile devices)</td>
<td>Regulation 3.8</td>
</tr>
</tbody>
</table>

* devices other than devices to be used for a special purpose (medical device used for a special purpose means a medical device to which regulation 3.10 applies; Part 7 of Schedule 3 provides procedures that must be applied to medical devices used for a special purpose)

** CAC – *conformity assessment certificate* (*conformity assessment certificate* means a certificate issued under section 41EE of the Act, this means certificate issued by the TGA) or Certificate issued under MRA in accordance with the relevant Part of Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*
## Conformity Assessment Procedures

<table>
<thead>
<tr>
<th>Medical device (non-IVD) – Class*</th>
<th>Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002</th>
<th>EC Certificate issued under MDD 93/42/EEC (Declaration must be made in accordance with Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002)</th>
<th>Provided under TG (MD) Regulations</th>
</tr>
</thead>
</table>
| **Class IIb**                     | CAC Full Quality Assurance - Part 1 (excluding clause 1.6 Design Examination) or CAC Type Examination - Part 2 plus CAC issued under either:  
  • Verification - Part 3 (for non-sterile devices) or  
  • Production Quality Assurance - Part 4 or  
  • Product Quality Assurance – Part 5 (for non-sterile devices) | • Annex II.3 or  
  • Annex III plus either:  
    – Annex IV (for non-sterile devices where specific batches are included on the certificate) or  
    – Annex V or  
    – Annex VI (for non-sterile devices) | Regulation 3.7 |
| **Class III**                     | CAC Full Quality Assurance - Part 1 (including clause 1.6 Design Examination) or CAC Type Examination - Part 2 plus CAC issued under either:  
  • Verification - Part 3 (for non-sterile devices) or  
  • Production Quality Assurance - Part 4 | • Annex II.3+II.4 or  
  • Annex III plus either:  
    – Annex IV (for non-sterile devices where specific batches are included on the certificate); or  
    – Annex V | Regulation 3.6 |
| **AIMD**                          |                                                                      | 90/385/EEC (AIMDD)                                                                                                           |                                  |
Examples

- Scope of the certificate
  - Device in the application → urinary catheter
  - EC Certificate scope → needles
    - Not acceptable
- Minimum conformity assessment procedure
  - Device in the application → Class IIb
  - EC Certificate → Annex V (Production quality assurance)
    - Not acceptable
  - EC Certificate → Annex V + Annex III (Type examination certificate)
    - Acceptable
Global Medical Device Nomenclature (GMDN)

- GMDN code
  - one of the characteristics that defines the kind of device
  - is to be consistent with the intended purpose of the device
- Linked to Class of medical device
  - relevant preferred term or
  - for Class I - the relevant template term (or preferred term if there is no relevant template term)

Manufacturer’s responsibility
GMDN examples

• Hypodermic needle, single-use, sterile [59230]
• Syringe, hypodermic, metered delivery, retractable needle [45042]
• Hevea-latex examination/treatment glove, powdered [47173]
• Hevea-latex examination/treatment glove, non-powdered, non-sterile [47172]
Information provided in the application

- Do not provide information that is not relevant in the application, for example:
  - Declaration of conformity made under EU Medical Device Directive
  - Test reports
- Ensure ‘Device Product Characteristics’ section in the application is correctly filled in
One page document

• Describe the device and intended purpose if needed in more detail
• Cite the classification rules in accordance with Schedule 2 of the Regulations and provide justification where required
• Explain how the kind of device is covered under the scope of certificate included in Manufacturer Evidence
• Make sure all the information is complete and correct
• Do not attach more than one page
Where do we go from here?

- Ensure all information provided in the application is correct.
- Any application may be selected for audit.
- Some applications must be selected for audit.
More information and guidance

Australian Regulatory Guidelines for Medical Devices

ComLaw : Database of Commonwealth law
Therapeutic Goods Act 1989, Chapter 4
Therapeutic Goods (Medical Devices) Regulations 2002

TGA website: News, consultations, guidance, subscribe to updates

Contact the TGA Medical Devices Branch
devices@tga.gov.au  1800 141 144
Guidance on the TGA website (www.tga.gov.au)
Thank you!
Manufacturer’s Evidence & Applications for ARTG Inclusion

What’s your success rate?
Today

Manufacturer’s Evidence and ARTG inclusions:

- Application processes by classification
- Preparation and checks to do
- TGA Business Services submission forms
- Common problems and ways to prevent or avoid them!

Some slides have legislation/guidance references where you can find more information for your specific needs.

Not covered:
- Conformity Assessment Procedures
- Audits
- Systems and Procedure Packs, IVDs
- Class III/AIMD UPI and Variants
- Clinical Evidence & Risk Assessment compliance
Sponsor Process Overview

**Class I**
- Preparation
- Complete & submit form
- No application fee
- Auto-inclusion
- ARTG Certificate available

**Class Is, Im, Ila or IIb**
- Preparation (+ Manufacturer’s Evidence is accepted on TGA Bus Serv)
- Complete & submit form
- Fee payment is processed (currently $960)
- TGA reviews application and may:
  - select for audit
  - approve the application
  - reject the application
- If approved:
  ARTG Certificate available

**Class III/AIMD**
- Preparation (+ Manufacturer’s Evidence is accepted on TGA Bus Serv)
- Complete & submit form
- Fee payment is processed (currently $1,235)
- TGA selects for audit
- Sponsor submits audit file & pays audit fee
- TGA reviews audit file and may:
  - Ask further questions
  - Approve the application
  - Reject the application
- If approved:
  ARTG Certificate available
Manufacturer’s Evidence

The first step in the TGA application process for Classes:
• I (supplied sterile or measuring)
• IIa and IIb
• III and AIMD

Consider this step as a key part of your Preparation
• Submit on TGA Business Services website well in advance

Manufacturer’s Evidence for medical devices (non-IVD) can be:
• CE Certificate (MDD or AIMDD)
• TGA Conformity Assessment Certificate
• System or Procedure Pack Declaration to Clause 7.5
• MRA Compliance Certificate
1. Complete the fields accurately using the details on the Evidence.

2. Attach the Evidence ONLY

3. Validate (if successful the submit button appears)

4. Submit
What is a medical device ARTG application?

ARTG Inclusion is for a **Kind of medical device**

(Section 41BE of The Act)

A medical device is of the same ‘kind’ if it has the same:

- Classification
- GMDN code
- Legally defined manufacturer
- Sponsor

And for Class III or AIMD, if it has the same:

- Unique Product Identifier (UPI)
Application Preparation

Know your product!

Product information from manufacturer (brochures, labelling, instructions for use)

- Is it a medical device?
- How is it packaged and supplied?
- How is it identified and tracked?
- Who is involved in manufacture and supply?
- Contain any medicine or materials of animal origin?
Application Preparation

Information for the TGA Business Services Device Application form

• **Is it:**
  - Sterile
  - Invasive
  - Reusable/Single Use
  - Active
  - Single product/system/procedure pack
  - Containing a medicine
  - Containing material/ingredients of microbial/recombinant/GMO/animal/human origin

• **Does it have appropriate evidence of Conformity Assessment?**
  - And have you submitted Manufacturer’s Evidence if Class Is/m, IIa, IIb, III or AIMD?
## Early checks to do

<table>
<thead>
<tr>
<th>Check</th>
<th>What?</th>
<th>How?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is it a medical device?</strong></td>
<td>• Check according to the <strong>TGA definition</strong></td>
<td>Refer to:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Section 41BD of the Act</td>
</tr>
<tr>
<td><strong>Risk Classification</strong></td>
<td>• Check correctly classified by manufacturer, according to <strong>TGA</strong></td>
<td>Refer to:</td>
</tr>
<tr>
<td></td>
<td>Classification Rules</td>
<td>• Schedule 2 of The Regulations (Regulation 3.2)</td>
</tr>
<tr>
<td><strong>Is the GMDN appropriate?</strong></td>
<td>• Can you see, based on product information, that the GMDN makes sense?</td>
<td>Refer to:</td>
</tr>
<tr>
<td></td>
<td>• Does it reflect the intended purpose?</td>
<td>• Regulation 1.7</td>
</tr>
<tr>
<td></td>
<td>• Must be a <strong>preferred term</strong> unless the device is Class I (template term allowed)</td>
<td>• ARGMD Section 10</td>
</tr>
<tr>
<td></td>
<td>• Check if the GMDN is on the TGA database</td>
<td>Use:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Product information (e.g. labelling, IFU, advertising)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Note:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• <em>If the GMDN code is not in the TGA database, ask for it to be added in advance by email to <a href="mailto:ebs@tga.gov.au">ebs@tga.gov.au</a></em></td>
</tr>
<tr>
<td><strong>Legally defined manufacturer</strong></td>
<td>• Verify who the legally defined manufacturer is</td>
<td>Refer:</td>
</tr>
<tr>
<td></td>
<td><em>Note: (manufacturer is: responsible for the design, production, packaging and labelling of the device before it is supplied under their name)</em></td>
<td>• Section 41BG of the Act</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• named manufacturer on label, IFU, certificates, advertising, etc. is consistent</td>
</tr>
</tbody>
</table>
Early checks to do

<table>
<thead>
<tr>
<th>Check</th>
<th>What?</th>
<th>How?</th>
</tr>
</thead>
</table>
| Conformity Assessment Evidence| • Need to check the appropriate level and route is held by the manufacturer  
✓ Dependant on Classification  
• Check Evidence is valid and correct  
✓ Make sure the certificate is accepted on TGA Business Services for Class Is, Im, Ila, Iib, III and AIMD | Refer to:  
• ARGMD Section 5 & 6  
• Check CE certificates contain all the information needed to be valid (ARGMD Section 7) |
| Essential Principles (EP) Compliance | • Are you confident and do you have evidence that the medical device meets the Australian EP?  
Note: Australian EP is NOT exactly the same as the European Essential Requirements (ER) | Refer to:  
• Schedule 1 of The Regulations (Regulation 2.1)  
• ARGMD Section 8  
Options:  
• Obtain completed EP Checklist  
• Obtain other documents to assure you that this is being met and is available |
Early checks to do

## Definitions

<table>
<thead>
<tr>
<th>Check</th>
<th>What?</th>
<th>How?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active medical device</td>
<td>• These definitions have <strong>very specific terminology</strong> and need to be <strong>carefully checked</strong></td>
<td>Refer to: • Regulation 1.3 (Dictionary)</td>
</tr>
<tr>
<td>Reusable surgical instrument</td>
<td>• If your product falls into any of these categories it <strong>could have a significant impact on the device class</strong></td>
<td>Refer to: • Regulation 1.3 (Dictionary)</td>
</tr>
<tr>
<td>Medical devices with a measuring function</td>
<td></td>
<td>Refer to: • Regulation 1.4</td>
</tr>
<tr>
<td>Central Circulatory System</td>
<td></td>
<td>Refer to: • Regulation 1.3 (Dictionary)</td>
</tr>
</tbody>
</table>
# Early checks to do

## Class III & AIMD

<table>
<thead>
<tr>
<th>Check</th>
<th>What?</th>
<th>How?</th>
</tr>
</thead>
</table>
| **Unique Product Identifier (UPI)** | - Check that you have a valid UPI and can demonstrate this to the TGA  
  *Note: UPI is the unique identifier given to the device by its manufacturer to identify the device and any variants*  
  | Refer to:  
  - Regulation 1.6  
  - ARGMD Section 10  
  Try to:  
  - Ensure the UPI is consistent on AU DoC, CE Certificates, Labelling, IFU, advertising and other documents |
| **Variants**                 | - Check that all devices you want to include in each application have allowable variants and you can demonstrate this to the TGA.  
  *Note: Variant means “A medical device, the design of which has been varied to accommodate different patient anatomical requirements or any other variation approved by the secretary for the purposes of this definition, if the variation does not change the intended purpose of the device”*  
  | Refer to:  
  - Regulation 1.3 (Dictionary)  
  - ARGMD Section 10  
  Try to:  
  - Demonstrate the variant is acceptable by provision of brochure, labelling or other technical documents |
Early checks to do

Is your Kind of Device subject to a **mandatory audit**?

Refer to: *Section 41FH of the Act; Regulation 5.3; ARGMD section 11 (below)*

<table>
<thead>
<tr>
<th>Implantable:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Intraocular Lens</td>
</tr>
<tr>
<td>- Contraceptive Device</td>
</tr>
<tr>
<td>- Breast Prostheses containing material of fluid consistency (other than water or saline solution only)</td>
</tr>
<tr>
<td>- Prosthetic Heart Valve</td>
</tr>
<tr>
<td>- Intended for disinfecting another medical device</td>
</tr>
<tr>
<td>- Class AIMD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Class III:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- procedure packs using a Clause 7.5 Declaration of Conformity</td>
</tr>
<tr>
<td>- Not assessed by the EC or EFTA Mutual Recognition Agreements</td>
</tr>
<tr>
<td>- Intraocular Visco Elastic Fluids</td>
</tr>
<tr>
<td>- Barrier indicated for contraception/prevention of transmission of disease in the course of penile penetration during sexual intercourse</td>
</tr>
</tbody>
</table>
Before you submit on TGA Business Services

✔ Obtain Manufacturer’s Australian Declaration of Conformity
  • To document the:
    o ‘kind of medical device’
    o standards applied
    o compliance with the Australian Essential Principles and legislation
  • Make sure you have the right template for class and conformity route
  • See https://www.tga.gov.au/industry/devices-forms-declaration-conformity.htm

✔ Ensure a written agreement is in place for post-market monitoring, vigilance and reporting obligations
  • Between AU Sponsor/Distributor and Manufacturer
  • For example, covering:
    o complaints and incident monitoring/reporting
    o Annual event reporting, etc.
TGA Application Forms

Information required is dependant on risk classification

• When you select the class the form will populate the various fields to be completed

• Common for all classes:
  • Intended Purpose
    • make sure this is consistent with other information in the application
  • Manufacturer Name and Address
  • GMDN Code and Description
  • Sponsor’s Declaration
## TGA Application Forms

<table>
<thead>
<tr>
<th>Class</th>
<th>Information needed in eBS</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>• 20-30 Device Product Characteristics questions <em>(Yes/No)</em></td>
</tr>
</tbody>
</table>
| I*(sterile)*, I*(measuring)*, IIa, IIb | • 11 Specific Details questions *(Yes/No)*  
• Select available *Manufacturer’s Evidence* |
| III AIMD | • 11 Specific Details questions *(Yes/No)*  
• Select available *Manufacturer’s Evidence*  
• UPI, Functional Description, # of devices covered & variants  
• Attach *Design/Type Examination Certificate* |
Additional Information

• Information in the TGA Business Services form is not always enough to give the TGA assessor a good understanding of the ‘kind of medical device’.

• If there is conflicting information, then the TGA assessor is likely to request information as part of an audit
  • This causes more work and delays for both the Industry and TGA

• If you know up front that there is additional information that will help the assessor, then you might want to attach a ONE PAGE ONLY document before you submit

Function to Attach/Add Supporting Information

This function allows the attachment of supporting documentation for the application. Its use is optional for Class I, IIm, Is, Ila and IIb medical devices, but Class III and AIMD applications must have a copy of the supporting Design Examination certificate, issued by the Conformity Assessment Body, attached. These applications will not validate without supporting documentation.

Add

No Attachments
ONE page attachment

Examples include:

- A Picture/diagram of the device to show:
  - the device itself
  - its packaging or components
  - how it interacts with users or patients
- A description of the device (not the intended purpose)
- A description of the mechanism of action (how it works)
- How the device is included in the scope of the CE Certificate
Sponsor’s Declaration

Declaration
I being a person authorised to make this application hereby certify that:

(a) devices of the kind in question are medical devices; and
(b) devices of that kind are intended for a specified purpose, as ascertained under The definition of a medical device; and
(c) the kind of device is correctly classified according to the medical device classifications; and
(d) devices of that kind comply with the essential principles; and
(e) I:
   (i) have available sufficient information to substantiate that compliance with the essential principles; or
   (ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(f) an appropriate conformity assessment procedure has been applied to devices of that kind; and
(g) I:
   (i) have available sufficient information to substantiate the application of those conformity assessment procedures; or
   (ii) have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(h) devices of that kind comply with every requirement (if any) relating to advertising applicable under the regulations; and
(i) devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and
(ii) devices of that kind are not to be used exclusively for one or more of the purposes specified under section 41BEA; and
(j) the information included in or with the application is complete and correct.

I understand the consequences of making a false declaration, as outlined below.
In electronically submitting this application to TGA, I hereby declare that in relation to this medical device the information given in this application and the above statements on this declaration form are current and correct.

PLEASE NOTE: A false declaration will result in the device entry being removed/cancelled from the ARTG.

I agree [ ] Yes [ ] No
Some Possible Problems

**Manufacturer’s Evidence applications:**
- Two or more certificates/documents attached – must be ONLY ONE per application
- ISO, EN, FDA, European Declarations, EC Design/Type Examination Certificates attached to Manufacturers Evidence applications
- Pages of CE Certificates/Evidence submitted are missing
- Certificate is not in English
- Information on the form doesn’t match the Evidence attached
- For Changes:
  - Additional information needed if change in Manufacturer Name/Address
  - Scope of the certificate has changed – If so, this must be answered YES on the application

**Medical Device Applications:**
- ‘Intended purpose’ doesn’t reflect GMDN code, Class, or specific details in the TGA form
- Product Characteristics aren’t consistent with the GMDN code, Class, or intended purpose, etc.
- Route of conformity (EC Certificate Annex) is not appropriate for the Class
- The TGA can’t identify where the product is covered in the EC Certificate scope
- The application isn’t linked to the correct Manufacturer’s Evidence
- Attachments contain irrelevant or conflicting information

**Other Administrative problems:**
- Fee payment not processed quickly
- Spelling errors
Ways to avoid problems

✓ **Do your preparation!** Time spent before submitting is well worth it and will increase your success rate

✓ Develop a good relationship & contract with manufacturer

✓ Make sure you have the correct and current Manufacturer’s Evidence, matching the medical device (and clearly identifiable in the scope)

✓ Accurately complete the TGA Business Services forms so that they properly represent the medical device you want to include

✓ Don’t submit extra certificates/documents that aren’t useful

✓ Make sure you understand your product and have verified the information you are submitting is correct *in advance*

✓ Make sure any extra information submitted is concise and accurate
References

• **The Act**
  
  Therapeutic Goods Act 1989

• **The Regulations**
  
  Therapeutic Goods (Medical Device) Regulations 2002

• **ARGMD**
  
  Australian Regulatory Guidance for Medical Devices
  
  (version 1.1 May 2011)