Devices
Sponsor Information Day

UNDERSTANDING THE TGA’S REGULATORY FRAMEWORK

SUPPORTING ORGANISATIONS —

www.sponsor-day.org
Medical devices (IVD) – application process

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Medical Devices (IVDs)

Applications for ARTG inclusion

Euan Miller
Application and Verification Section
Medical Devices Branch
Devices Sponsor Information Day

15 October 2015
Purpose

Facilitate better understanding of the regulatory requirements for IVD medical devices

ARTG inclusion – explain the process and give some examples
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*
In vitro diagnostic (IVD) medical device

- A reagent, calibrator, control material, kit, specimen receptacle, instrument, software, equipment or system
- Intended for the in vitro examination of human specimens for
  - giving information about a physiological or pathological state
  - giving information about a congenital abnormality
  - determining safety and compatibility with a potential recipient
  - monitoring therapeutic measures

*Dictionary, Therapeutic Goods (Medical Devices) Regulations 2002*
Examples
Types of IVD medical devices

• Intended to be used by:
  – health professionals in the laboratory
  – health professionals at the point of care
  – lay-person (self-testing)

• Does not include Research Use Only (RUO) or Analyte Specific Reagents (ASR)
ARTG inclusion

• Any IVD medical device must be included in ARTG
  - Transitional provisions ended on 30 June 2015
• Except:
  - Devices for which effective applications for inclusion in the ARTG were submitted before the end of transitional period but not yet finalised
  - In-house IVD medical devices (transitional provisions until 30 June 2017)
• 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 and level of risk of the device

Conformity assessment procedures

Essential principles for safety and performance

Post-market monitoring
Process for ARTG inclusion

1. Sponsor
   - Submit application for Class I IVD or Class I (not IVD)
   - Pay application fee
   - Application effective?
     - YES: Audit?
       - YES: TGA requires information & audit fee (if applicable)
       - NO: Decision to include (ARTG entry)
     - NO: Decision to include (ARTG entry)
   - Application lapses if fee not paid or information not provided
   - Audit assessment
   - Recommendation
     - YES: Decision
     - NO: Notification (TBS email)

2. Decision
   - YES: Notification (TBS email)
   - NO: Notification (sent with reasons)

3. 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 1 IVD

**Acceptable certificates**

- TGA conformity assessment certificate
- EC Certificate issued in accordance with IVDD 98/79/EC
- ISO 13485 (CMDCAS ISO 13485 or IAF ISO 13485)
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 Class 4 IVD – conformity assessment certificate must be issued by the TGA for the device
  - Must not contain information that is false or misleading in a material particular
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
- 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
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 (for Class 4 IVDs)

*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

- Blood glucose monitoring system (BGMS) (including strips) AND test strips AND controls
  - ✔ These devices are of the same kind
- BGMS (excluding strips) AND test strips AND controls
  - ✗ 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 (labeling, 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)
IVD medical devices are classified having regard to the intended purpose of the device and its risk to public health and/or personal risk:

- **Class 1 IVD** – no public health risk or low personal risk
- **Class 2 IVD** – low public health risk or moderate personal risk
- **Class 3 IVD** – moderate public health risk or high personal risk
- **Class 4 IVD** – high public health risk

*Therapeutic Goods (Medical Devices) Regulations 2002, division 3.1 and schedule 2A*
Classification (Schedule 2A)

- Rule 1.1: Class 4
- Rule 1.2: Class 3/4
- Rule 1.3: Class 3
- Rule 1.4: self-testing
- Rule 1.5: QC
- Rule 1.6: Class 1
- Rule 1.7: Class 2
- Rule 1.8: Export only

Session 3B – Medical Devices (IVDs) - Application process
Classification examples

• Class 1 IVDs
  - Microbiological culture media; instruments/analysers

• Class 2 IVDs
  - Pregnancy self-tests, H&E stain

• Class 3 IVDs
  - sexually transmitted diseases; genetic tests (inc. FISH)

• Class 4 IVDs
  - screen blood donors for HIV & HCV; ABO
Common questions

• Pathogens listed on the Australian National Notifiable Disease Surveillance System (NNDSS) list
• Human genetic testing
• Patient selection* for:
  i. selective therapy and management
  ii. disease staging
  iii. diagnosis of cancer

*An IVD medical device would fall into Class 2 IVD if
  a) a therapy decision would usually be made only after further investigation; or
  b) the device is used for monitoring
Conformity assessment procedure

Declaration of conformity

- To be provided with the application:
  - ✓ Class 3 IVDs
- Must be made in accordance with Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*
- Must contain correct information (including Certificate number appropriate for the device)
- Templates available
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

• Depends on Class of IVD device
  - relevant preferred term or
  - Level 1, Level 2 or Level 3 collective term (CT)

Manufacturer’s responsibility
# GMDN examples

<table>
<thead>
<tr>
<th>IVD medical device</th>
<th>GMDN</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV1/HIV2 antigen IVD, kit, immunochromatographic test (ICT) rapid</td>
<td>[30832]</td>
</tr>
<tr>
<td>Human immunodeficiency viruses (HIV)</td>
<td>[CT284]</td>
</tr>
<tr>
<td>Viral Infectious disease IVDs</td>
<td>[CT355]</td>
</tr>
<tr>
<td>Infectious disease IVDs</td>
<td>[CT701]</td>
</tr>
</tbody>
</table>

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# GMDN – more examples

<table>
<thead>
<tr>
<th>IVD medical device</th>
<th>GMDN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple urine analyte IVD, kit, colourimetric dipstick, rapid</td>
<td>[30225]</td>
</tr>
<tr>
<td>Urine screening IVDs</td>
<td>[CT1246]</td>
</tr>
<tr>
<td>Clinical chemistry biological screening IVDs</td>
<td>[CT1236]</td>
</tr>
<tr>
<td>Clinical chemistry IVDs</td>
<td>[CT287]</td>
</tr>
</tbody>
</table>
GMDN – one more example

<table>
<thead>
<tr>
<th>IVD medical device</th>
<th>GMDN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose monitoring system IVD, home use/point-of-care</td>
<td>[30854]</td>
</tr>
<tr>
<td>No relevant level 3 Collective Term (CT)</td>
<td></td>
</tr>
<tr>
<td>Clinical chemistry substrate IVDs</td>
<td>[CT833]</td>
</tr>
<tr>
<td>Clinical chemistry IVDs</td>
<td>[CT287]</td>
</tr>
</tbody>
</table>
For any type of IVD device referred to in Regulation 5.3(1)(j), the application form requires applicants to enter the names of all individual devices of the kind as these devices appear on the labelling.
Procedure Packs containing IVD

- Goods in the package are a system or procedure pack if
  - the goods are for use as a unit, either in combination or in a medical or surgical procedure and
  - the package contains at least one medical device

- Classification
  - is determined by the highest class of device included in the pack or
  - if all devices are of the same class, it is classified according to the primary intended purpose of the system or procedure pack
Procedure packs
Reg. 3.3 (9) – highest classification

IVD (Class 3) + MD (Class Ila) = Class 3 IVD Procedure Pack

Session 3B – Medical Devices (IVDs) - Application process
Procedure packs
Reg. 3.3 (10) same class

**Diagram:**
- IVD (Class 1)
- MD (Class I)
- Class 1 IVD or Class I MD Procedure Pack

**Intended purpose**
One kind of device

Supplied as a SINGLE unit

- Instrument
- Assay Kit
- Control/Calibrators
Devices are not of the same kind

System

- Instrument (Class 1 IVD)
- Accessories
- Assay Kit
- Controls / Calibrators

Session 3B – Medical Devices (IVDs) - Application process
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
Further information

TGA website

- IVD medical devices regulation basics
- News, consultations, guidance, subscribe to updates

ComLaw: Database of Commonwealth law

- *Therapeutic Goods Act 1989*, Chapter 4
- *Therapeutic Goods (Medical Devices) Regulations 2002*

Contact the TGA Medical Devices Branch

- devices@tga.gov.au  1800 141 144
The Application Process

• **Introduction**

  • This presentation will step through the process of making an application for inclusion on the ARTG
  
  • The format is screen shots highlighting the key steps
  
  • Two scenarios will be presented
    • An uncomplicated Class 2 IVD
    • A Class 3 IVD requiring higher level scrutiny
The Application Process

• Before you start

  • The appropriate Manufacturer’s Evidence for your IVD must be submitted and accepted.
  
  • Know the Class of your IVD.
  
  • Know the GMDN term for your IVD.
  
  • Have at hand any other evidence that will be required, such as
    • Declaration of Conformity (for all Class 3)
    • Design Examination Certificate (for all Class 4)
https://business.tga.gov.au
Welcome

What would you like to do today?

View my organisation

News panel

- Issues affecting documentation attached to some GMP clearance applications - 29 July 2015
  The TGA has become aware of issues affecting documentation attached to some clearance applications. The issue may result in evidence attached to the application being invalid.

- Clarification on the use of hyphens in TGA approved terminology for medicines
  The Ingredient Table within TGA Business Services provides the approved names for ingredients used in therapeutic goods. When you review these entries...

Work in progress

<table>
<thead>
<tr>
<th>Drafts</th>
<th>Submissions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received</td>
<td>Identifier</td>
</tr>
<tr>
<td>No data available in table</td>
<td></td>
</tr>
</tbody>
</table>
Navigation buttons top and bottom on each page
Device Application

Application Details

* Application for:
* Sponsor's own reference:

Sponsor Details

Agent name:
* Applicant address:
* Sponsor name:
* Contact name:
Contact email:
karen.macleod@mpbio.com

Address Details

In making a product application for entry on the Register, two critical addresses are to be associated with the product, the sponsor's billing address and regulatory correspondence address. Please select the relevant address for this product entry.

Note: The addresses are read from your electronic Client record. If you require reference to a different address, it must be notified to the TGA for inclusion in your address list so that this application can be completed. Please use the Client web update form to nominate the new address details.

Billing address:
Regulatory correspondence address:

This application is to:

* Manufacturer's intended purpose of the device

This should be a detailed description of the manufacturer's intended purpose and should closely align with the relevant GMDN description. Note: This field is up to approximately 350 words.

Specific Details

* Is the device, or any form of the device, supplied sterile?
* Is the device intended to be invasive?
* Is the device, or any form of the device, intended for single use?
* Is the device an active device?
* Does the device contain material or ingredients of microbial origin?
Free text
Page 1

Application Details
- Application for:
  - Medical Device - IVD
  - IVD Assay

Sponsor Details
- Agent name:
- Applicant address:
- Sponsor name:
- Contact name:
- Contact email:

Address Details
In making a product application for entry on the Register, two critical addresses are to be associated with the product, your billing address and regulatory correspondence address. Please select the relevant address for this product entry. Note: The addresses are read from your electronic Client record. If you require reference to a different address, it must be notified to the TGA for inclusion in your address list so that this application can be completed. Please use the Client web update form to nominate the new address details.

Billing address:
- Regulatory correspondence address:
  - SEVEN HILLS NSW 1730
  - SEVEN HILLS NSW 1730

This application is to:
- Class:
- Fee: $960.00

Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?
- Yes ☐ No ☐

Will you be applying for listing of this product on the Prosthesis List?
- Yes ☐ No ☐

Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?
- Yes ☐ No ☐

*These questions relate to reimbursement under the Health Technology Assessment (HTA) process. For further information/guidance on completing these questions please refer to the (?i) icon.

Manufacturer’s intended purpose of the device:
*This should be a detailed description of the manufacturer’s intended purpose and should closely align with the relevant GMDN description. Note: This field is up to approximately 350 words.

Device Product Characteristics
Please note that you are legally required to supply accurate responses to the device product characteristic’s questions, therefore you must ensure that you are fully informed before entering information. Penalties apply for false or misleading information.

- Does this application include any IVDs that are:
  - Class 3 and intended for detecting the presence of or exposure to a sexually transmitted agent
  - For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
  - To be supplied for use in a national disease screening program
  - Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
  - To be supplied under the Pharmaceutical Benefits Scheme
  - Intended for point-of-care testing
  - Intended for self-testing? (26)
- Does this application include a system or procedure pack? (064)
- ☐ Yes ☐ No

...
The Manufacturer’s intended purpose of the device should include a brief but accurate description regarding the use of the kind of the device. This may include:
- How the device is to be used;
- The circumstances in which the device would be used; and
- Any limitations of the device.

The manufacturer’s intended purpose should closely align with the selected GMDN.

The description should be limited to 350 words. It should not include a listing of components or parts.

Device Product Characteristics
Please note that if you are legally required to supply accurate responses to the device product characteristic’s questions, therefore you must ensure that you are fully informed before entering information. Penalties apply for false or misleading information.

- Does this application include any IVDs that are:
  - Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent
  - For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
  - To be supplied for use in a national disease screening program
  - Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
  - To be supplied under the Pharmaceutical Benefits Scheme
  - Intended for point-of-care testing
  - Intended for self-testing? (Q80)
  - Does this application include a system or procedure pack? (Q64)

- Yes  No
The Application Process

Scenario 1

• Class 2

• Manufacturer Evidence CMDCAS ISO 13485 Certificate

• “No” to device product characteristics questions
Application Details

- Application for:
  - Medical Device - IVD

Sponsor's own reference:

- Sponsor name:
- Contact name:
- Contact email:

Address Details

- Regulatory correspondence address:
  - SEVEN HILLS NSW 1730

Sponsor Details

- Agent name:
- Applicant address:
- Sponsor name:
- Contact name:
- Contact email:

Application Class Details

- Class:
  - Class 2
  - $960.00

- Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?
  - Yes

- Will you be applying for listing of this product on the Prothesis List?
  - Yes

- Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?
  - Yes

Manufacturer's intended purpose of the device

- This should be a detailed description of the manufacturer's intended purpose and should closely align with the relevant GMDCN description. Note: This field is up to approximately 350 words.

Device Product Characteristics

Please note that you are legally required to supply accurate responses to the device product characteristic's questions, therefore you must ensure that you are fully informed before entering information. Penalties apply for false or misleading information.

- Does this application include any IVDs that are:
  - Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent
  - For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
  - To be supplied for use in a national disease screening program
  - Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
  - To be supplied under the Pharmaceutical Benefits Scheme
  - Intended for point-of-care testing
  - Intended for self-testing? (Q58)

- Does this application include a system or procedure pack? (Q64)

- Yes
- No
Only manufacturers with certificates which cover the type and/or class of this application (Class 2) are shown.
The Application Process

Scenario 2

• Class 3

• Manufacturer Evidence TGA Conformity Assessment Certificate

• “Yes” to device product characteristics questions

• Testing for a sexually transmitted agent
Application Class Details

Class: Class 3
Fee: $360.00

Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?
- Yes
- No

Will you be applying for listing of this product on the Prosthesis List?
- Yes
- No

Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?
- Yes
- No

*These questions relate to reimbursement under the Health Technology Assessment (HTA) process. For further information/guidance on completing these questions please refer to the (?) icon.

Manufacturer's intended purpose of the device:
*This should be a detailed description of the manufacturer's intended purpose and should closely align with the relevant GMDN description. Note: This field is up to approximately 350 words

This IVD is to detect antibodies to infectious agents in human specimens.

Device Product Characteristics

Please note that you are legally required to supply accurate responses to the device product characteristic's questions, therefore you must ensure that you are fully informed before entering information. Penalties apply for false or misleading information.

*Does this application include any IVDs that are:
- Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent
- For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
- To be supplied for use in a national disease screening program
- Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
- To be supplied under the Pharmaceutical Benefits Scheme
- Intended for point-of-care testing
- Intended for self-testing? (Q60)
- Does this application include a system or procedure pack? (Q64)
- Yes
- No

IVD Name and Category

* Name of IVD:
* Category:

Infectious Disease IVD
- Class 3 sexually transmitted agent testing
- Managing/monitoring treatment of infections diagnosed using Class 4 IVD
- National disease screening program
- Non-assay specific quality control material for monitoring a Class 4 IVD
- Pharmaceutical Benefits Scheme
- Point of care testing
- Self Testing

Add

1. Infectious disease IVD
   Class 3 sexually transmitted agent testing
TGA Conformity Assessment Certificate = the application is *unlikely* to be selected for audit
The Application Process

**GMDN selection**
- The same for either scenario
Page 2B - Manufacturing Details (Other Classes)

1. Select Manufacturer for Evidence:
   Only manufacturers with certificates which cover the type and code of the device are eligible. The manufacturer site is provided for reference.

2. Select Manufacturer Evidence Number (Hold down the Ctrl key to select multiple numbers).

For Information Only
Certification Issued By:

GMDN Code and Description:

Search for:
- Bacterial infectious disease IVDa[CT353]
- Fungal infectious disease IVDa[CT354]
- Multiple infectious organism IVDa[CT923]
- Parasitic infectious disease IVDa[CT356]
- Prion infectious diseases IVDa[CT825]
- Viral infectious disease IVDa[CT355]

Search:
GMDN Text: infectious

GMDN Code:

View Definition:
- Bacterial infectious disease IVDa[CT353]
- Fungal infectious disease IVDa[CT354]
- Multiple infectious organism IVDa[CT923]
- Parasitic infectious disease IVDa[CT356]
- Prion infectious diseases IVDa[CT825]
- Viral infectious disease IVDa[CT355]

The GMDN is a nomenclature system for medical devices for the purpose of exchange of regulatory data. The coding follows strict rules where the term is made up of a base concept (noun or phrase) followed by one or more qualifiers. For searching purpose, the system also employs synonyms.

Search:
- Go (Minimum 3 characters to search for text)
- Keywords including AND, AND NOT OR may be used to refine your search

The "Synonym" label identifies terms by common usage descriptions that link to a primary GMDN term. When the synonym is selected, the primary term is displayed through the "View Definition" and it is the primary code that is passed to the DEAL form.
Page 2B - Manufacturing Details (Other Classes)

- Select Manufacturer for Evidence:
  - Only manufacturers with certificates which cover the type and/or class of this application (Class 2) are shown.
  - Manufacturer Site:
  - Manufacturer Evidence Number (Hold down the Ctrl key when selecting multiple ME):

For Information Only:
Certification Issued By:

- GMDN Code and Description:
  - Search

Application Identifier: DV-20154VA-17595-1

MP Biomedicals LLC [United States Of America] [58221]
Solon OH 44139 United States Of America S [194937]
DV-2012-MG- M58983

[Highlighted text]
Multiple infectious organism IVDs[CT923]
The Application Process

Finalisation
Class 2
• Make the declaration, Validate and submit
Page 5 - Applicant's Certification

Summary Information

Application ID: DV-2015-IVD-17506-1
Submission date: 08/10/2015
Application for: Medical Device - IVD

Will you be applying for listing of this product or procedure in the Medicare Benefits Schedule (MBS)?
- No

Will you be applying for listing of this product on the Prostheses List?
- No

Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?
- No

Sponsor name:
NP BiomediCare Australia Pty Ltd

Application fee:
$601.03

Does this application include any IVDs that are:
- Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent
- For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
- To be supplied for use in a national disease screening program
- None
- Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
- To be supplied under the Pharmaceutical Benefits Scheme
- Intended for point of care testing
- Intended for self-testing? (Q86)
- No

Does this application include a system or procedure pack? (Q94)
- No

Manufacturer name:

Manufacturer address:

GUDH code and term:

Intended purpose:

This function allows the attachment of supporting documentation for the application. Its use is optional for Class 1 and 2 applications, but Class 3 must have a copy of the supporting Declaration of Conformity and Class 4 must include a Design or Type certificate, attached. These applications will not validate without supporting documentation.

Declaration

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

I understand the consequences of making a false declaration, as outlined below.
(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 have available sufficient information to substantiate that compliance with the essential principles; or
(f) I have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(g) I have an appropriate conformity assessment procedure has been applied to devices of that kind; and
(h) I have available sufficient information to substantiate the application of those conformity assessment procedures; and
(i) I have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and
(j) devices of that kind comply with every requirement if (any) relating to advertising applicable under the regulations; and
(k) I do not contain substances that are prohibited from the purposes of the Customs Act 1901, and
(l) I included in or with the application is complete and correct.

In electronically submitting this application to TOA, I hereby declare that in relation to this device the information given in this application is current and correct.

In electronically submitting this application to TOA, I hereby declare that in relation to this 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

(End of Form)
The Application Process

Finalisation
Class 3
• Declaration of Conformity to be attached
Declaration

I, being a person authorized,

under the regulations to make

the declaration contained in

this application for the

purpose of conforming to

the requirements of

the regulations,

do hereby declare that

the information contained in

this application is true and

correct.

In electronically submitting

this application to TGA, I

hereby declare that in

relation to this therapeutic device

the information given in this

application is current and correct.

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
Declaration of Conformity

I, the person authorised to make this application hereby certify that:

I understand the consequences of making a false declaration, as outlined below:

a) Devices of the kind in question are medical devices.

b) Devices of that kind are intended for a specified purpose, as ascertained under the definition of a medical device.

c) The kind of device is correctly classified according to the medical device classifications.

d) Devices of that kind comply with the essential principles.

(i) I have available sufficient information to substantiate that compliance with the essential principles;

(ii) If I have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations, and

(iii) If an appropriate conformity assessment procedure has been applied to devices of that kind, and

(iv) If I have available sufficient information to substantiate the application of those conformity assessment procedures;

or (i)(ii) If I have procedures in place, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations, and

(v) Devices of that kind comply with every requirement (if any) relating to advertising applicable under the regulations, and

(vi) Devices of that kind do not contain substances that are prohibited imports for the purposes of the Customs Act 1901, and

(vii) The information included in or with the application is complete and correct.

In electronically submitting this application to TGA, I hereby declare that in relation to this therapeutic device the information given in this application is current and correct.

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

(End of Form)
Page 5 - Applicant's Certification

Summary Information

- Application ID: DV-2015-IVA-17302-1
- Submission date: 08/10/2015
- Application for: Medical Device - IVD
- Application type:
  - Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)? No
  - Will you be applying for listing of this product on the Prostheses List? No
  - Will you be applying for listing of this product on the Co-dependent or hybrid technology application list? No
- Sponsor name: MP Biomedicals Australasia Pty Ltd
- Class: IVD test
- Application fee: $960.00

Does this application include any IVDs that are:

- Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent Yes
- For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
- To be supplied for use in a national disease screening program
- Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
- To be supplied under the Pharmaceutical Benefits Scheme
- Intended for point-of-care testing
- Intended for self-testing? (Q56) No

xxx Class 3 sexually transmitted agent testing

Manufacturer name: MP Biomedicals Asia Pacific Pte Ltd (Singapore)
Manufacturer address: 2 Pioneer Place Singapore 627885 Singapore S 304956
GMDC code and term: Multiple infectious organism IVDs[CT923]
## IVD Device Application

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<td><strong>Medical Device - IVD</strong></td>
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<td><strong>Sponsor Fee:</strong></td>
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<tr>
<td><strong>Agent Name:</strong></td>
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<td><strong>Contact Email:</strong></td>
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</tbody>
</table>

**SEVEN HILLS NSW 1730**

MP Biomedicals Australasia Pty Ltd
Karen MacLeod
karen.macleod@mpbio.com
Page 5 - Applicant’s Certification

Summary Information

Application ID: DV-2015-IVA-17302-1
Submission date: 09/10/2015
Application for: Medical Device - IVD
Application type:
Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)? No
Will you be applying for listing of this product on the Prostheses List? No
Will you be applying for listing of this product on the Co-dependent or hybrid technology application list? No
Sponsor name: MP Biomedicals Australasia Pty Ltd
Sponsor own reference: IVD test
Class: Class 3
Application fee: $960.00

Does this application include any IVDs that are:
- Class 3 and intended for detecting the presence of, or exposure to, a sexually transmitted agent
- For managing and monitoring the treatment of infections diagnosed using Class 4 IVD
- To be supplied for use in a national disease screening program
- Non-assay specific quality control material that is intended for monitoring a Class 4 IVD
- To be supplied under the Pharmaceutical Benefits Scheme
- Intended for point-of-care testing
- Intended for self-testing? (Q60)
- Does this application include a system or procedure pack? (Q64)
  Yes

xxx: Class 3 sexually transmitted agent testing

Manufacturer name: MP Biomedicals LLC (United States Of America)
Manufacturer address: 84139 United States Of America S [ 194937]
Manufacturer evidence: MP Solon Endocrine and Neonatal IVDs
GMDN code and term: Multiple infectious organism IVDs!CT9231

Questions?
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