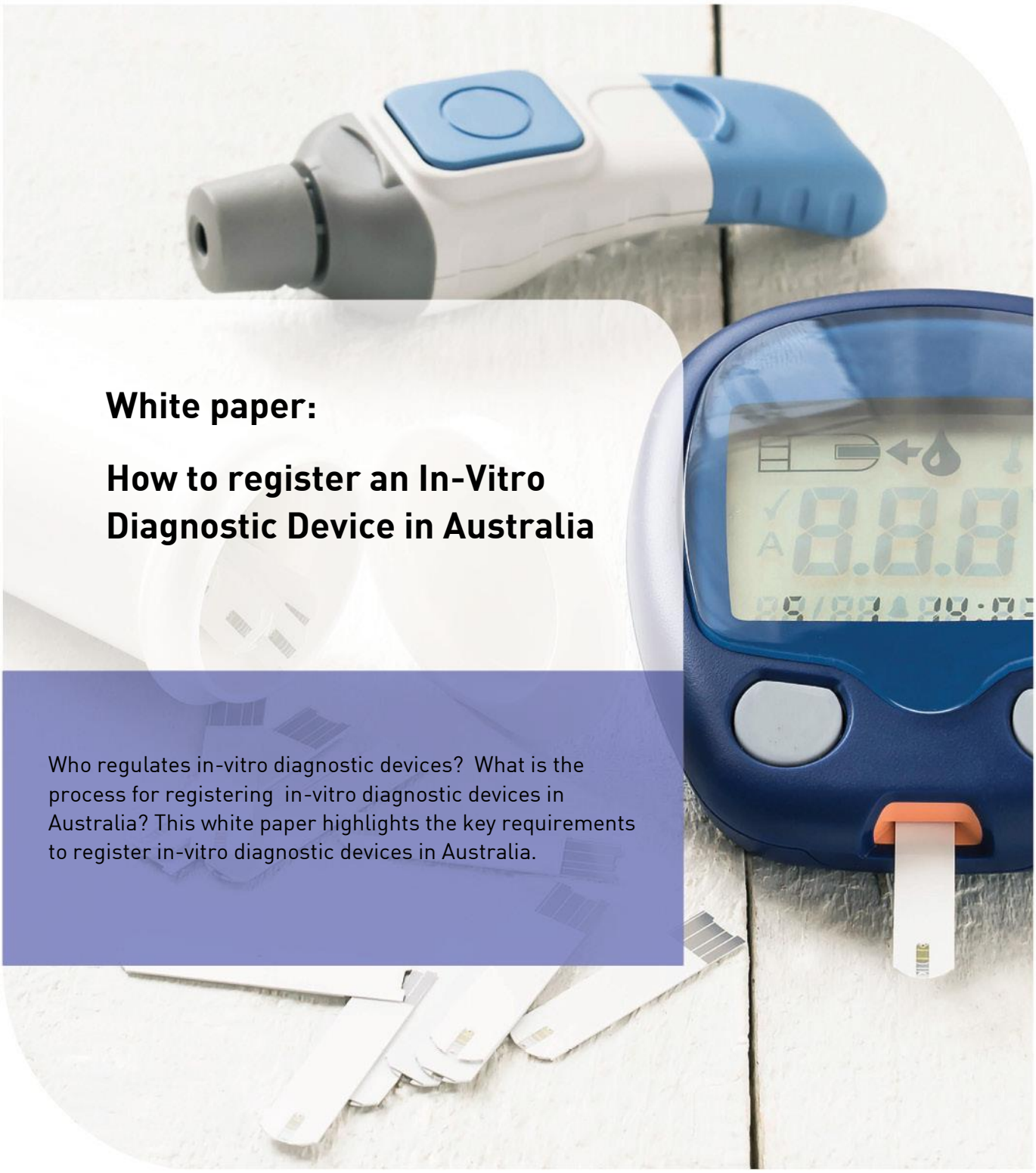

White paper:

How to register an In-Vitro Diagnostic Device in Australia

Who regulates in-vitro diagnostic devices? What is the process for registering in-vitro diagnostic devices in Australia? This white paper highlights the key requirements to register in-vitro diagnostic devices in Australia.

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What is an In-Vitro Diagnostic device?

An In-Vitro Diagnostic (IVD) device is used alone, or in combination with other diagnostic devices for in-vitro diagnostic procedures. An IVD device usually comprises pathology tests and related instrumentation used to conduct testing on human blood or tissue samples to assist in clinical diagnosis. For the purposes of this White Paper, IVD devices exclude devices that are intended for general laboratory use.

For additional information on registering medical devices, refer to the PharmOut White Paper: How to Register a Medical Device in Australia.

Australia's IVD Device Regulatory System

A new regulatory framework was introduced in July 2010 to ensure all IVDs are subjected to a level of regulatory scrutiny commensurate with the risks associated with their use. Based on the *Therapeutic Goods Regulations (Medical Devices)* 2002 and the recommendations from the Global Harmonised Task Force (GHTF), IVDs have been included as a subset of medical devices.

The Australian IVD regulatory system:

- requires inclusion of all IVDs for therapeutic use in the Australian Register of Therapeutic Goods (ARTG).
- requires compliance of all IVDs with a set of Essential Principles for the quality, safety and performance of IVDs.
- includes an IVD classification scheme based on different levels of risk for each classification.
- offers a selection of Conformity Assessment procedures based on the risk classification, so manufacturers can indicate initial and ongoing compliance with the TGA's Principles.
- requires manufacturers to demonstrate that the Essential Principles and Conformity Assessment procedures have been met through the compliance with recognised standards.
- makes provision for post-market activities, including compliance testing, adverse event reporting and IVD recalls.
- provides mechanisms for access to IVDs not entered on the ARTG, in cases of special need.
- allows a transition period to enable current manufacturers and sponsors of IVDs that are currently listed, registered or exempt by TGA to fulfill the requirements of the new framework. The transition period runs until 1 July 2014.

Kinds of IVD devices

Manufacturers or sponsors can opt to submit an application for including an IVD device in ARTG according to a range of devices of a 'same kind', rather than an individual device. According to the *Therapeutic Goods Act* 1989, section 41BE, medical devices are considered to be of the same kind as another medical device if they:

have the same sponsor, manufacturer, device nomenclature system code and medical device classification, and

are the same in relation to such other characteristics as the regulations prescribe, either generally or in relation to medical devices of the kind in question.

Classification of IVD devices

IVD devices are grouped into four classes based on the level of risk, as described in the *Therapeutic Goods (Medical Devices) Regulations* 2002, Regulation 3.1, Subregulation 3.2(2), Schedule 2A, and Subregulation 3.3(2).

Class	Level of Risk	IVD examples
I IVD	No public health or low personal risk	A specimen receptacle, a microbiological culture medium, enzyme immunoassay analyser
2 IVD	Low public health or moderate personal risk	Non-assay specific control plasmas for use in coagulation studies, biochemistry tests for vitamins and hormones
3 IVD	Moderate public health risk or moderate personal risk	Tests for tumour markers, test to detect sexually transmitted diseases, pharmacogenetic tests
4 IVD	High public health risk	Assays for clinical diagnosis of Hepatitis B, Hepatitis C and HIV

Unique Product Identifiers (UPI)

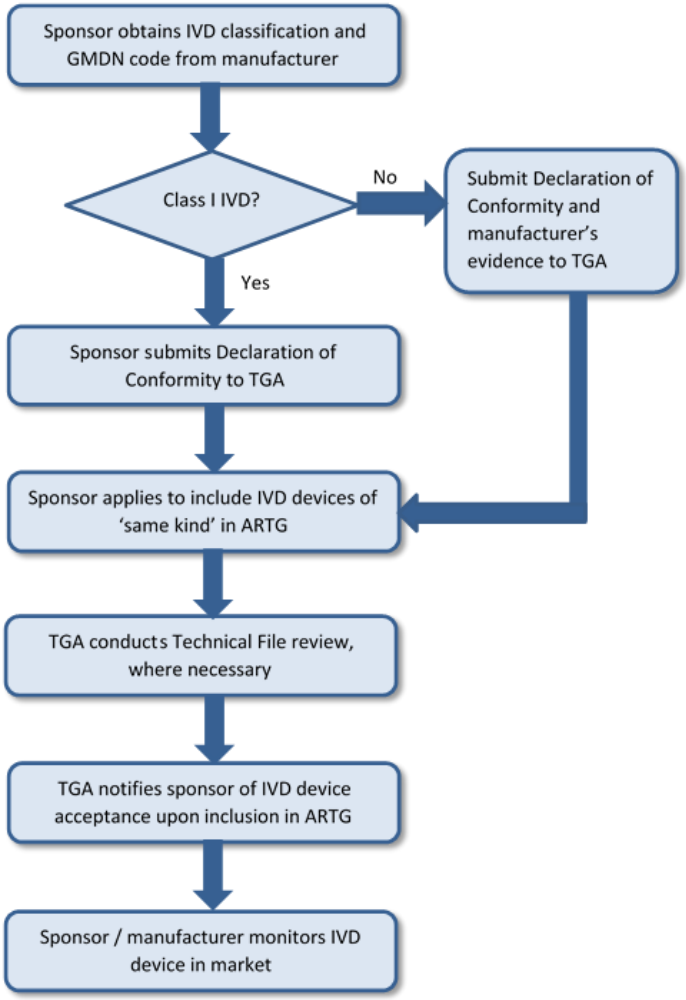
The UPI comprises the combination of words, numbers, symbols or letters assigned by the IVD manufacturer to uniquely identify an individual IVD, or a combination of IVDs which together constitute an IVD closed system. The IVD closed system is a combination of reagents, calibrators and quality control materials that share a common intended purpose and are to be used only in combination with each other as components of a single assay.

For example, a Class 1 IVD immunohaematology reagent is considered to be the 'same kind' as another Class 2 IVD immunohaematology reagent if both IVD devices have the same:

- legal manufacturer.
- sponsor.
- classification.
- Global Medical Device Nomenclature (GMDN) code.

How does the TGA approve IVD devices to be supplied in Australia?

TGA approves supplied IVD devices in Australia according to the process below.



Key conditions for including an IVD device in ARTG:

- If the IVD belongs to Class 2 , 3 or 4 and is manufactured in Australia, the sponsor must obtain a TGA Conformity Assessment certificate from the manufacturer.
- If a Technical File review is required, the TGA sends an invoice to the sponsor for an assessment fee and requests supporting information, which is due in 30 days. The TGA conducts a Technical File review for IVDs that are used for:
    - self-testing.
    - point of care tests.
    - testing for notification of sexually transmitted infections on the Australian National Notifiable Diseases List.
    - non-assay specific quality control material.
    - monitoring treatments of infections diagnosed using Class 4 IVDs.

Responsibilities of IVD device manufacturers and sponsors

If you are either an IVD device manufacturer or sponsor, refer to the table below.

IVD device manufacturer	IVD sponsor
Performs design, manufacture, packaging, labelling of the IVD device.	Establish an agreement with manufacturer to obtain and submit information to the TGA upon request.
Determine the intended purpose, IVD classification and GMDN code.	Obtain and submit information based on the Essential Principles to TGA upon request.
Establish processes to conform with Essential Principles.	Ensure selection of a suitable Conformity Assessment procedure and maintain evidence.
Submit Conformity Assessment evidence to the TGA during application to include an IVD device in ARTG.	Attain a copy of the Conformity Assessment evidence from the IVD device manufacturer to submit to the TGA (e.g. ISO 13485 Certificate).
Notify the TGA via the legal representative if the manufacturer dies, is declared bankrupt or if the body corporate is shut down, within three months of the occurrence.	Apply ongoing post-marketing surveillance and vigilance reporting for the IVD.
	Submit samples of IVD device to TGA upon request.
	Permit TGA authorised personnel to enter and inspect IVD manufacturing sites.
	Ensure compliance of advertising material with Therapeutic Goods. Advertising Code 2007.

Demonstrating compliance with the Essential Principles

The IVD device manufacturer is required to demonstrate compliance with the relevant Essential Principles requirements. There is an accessible Essential Principles checklist on the TGA website for this purpose.

The Essential Principle requirements include:

- documented review of appropriate published literature.
- technical documentation, including risk analysis and procedures, to indicate compliance with relevant requirements and standards.
- specific relevant documentation for IVD devices (e.g. specimen type and collection method, reagent description, assay procedure, clinical evidence).

IVD manufacturers who require a Conformity Assessment Certificate

The IVD device manufacturers that require a Conformity Assessment Certificate to supply IVD devices in Australia, regardless of possessing overseas certificates or licences, are manufacturers of class 4 IVDs, including class 4 in-house IVDs.

Exceptions apply to IVD device manufacturers below:

- Class I IVDs.
- IVD systems and procedure packs that have undergone special Conformity Assessment procedures.
- devices supplied to individuals for clinical trials, Special Assess Schemes, Authorised Prescribers, personal importation.
- Class I to 3 in-house IVDs.

Issuance of a Conformity Assessment Certificate

The TGA will issue a Conformity Assessment certificate once a Conformity Assessment is completed for the IVD based on:

- confirmation of the appropriateness of the selected Conformity Assessment procedure.
- systematic examination of the technical documentation, including high-risk IVD design.
- an on-site audit of the manufacturing premises, where necessary.
- re-certification of Conformity Assessment evidence that is due to expire, if required.

Declaration of Conformity (DoC)

After obtaining the relevant Conformity Assessment evidence, an Australian DoC must be generated to declare that the IVD device complies with:

- the applicable provisions of the Essential Principles.
- the classification rules.
- an appropriate Conformity Assessment procedure.

Conditions of inclusion in ARTG for IVD devices

The conditions for inclusion of IVD devices in ARTG are listed below.

Automatic conditions	Conditions which may be imposed	Conditions imposed after inclusion
Authorised person to enter and conduct inspection, obtain samples and documents	Manufacture of IVD devices	New, modified or removed conditions for avoiding imminent risks of death, injury or illness, when necessary, upon TGA notification
Deliver requested samples to the TGA.	Storage and disposal of IVD devices	Other specified TGA conditions, imposed not earlier than 20 days from notice date, when necessary.
Submit information on Conformity Assessment and quality management system changes	Maintenance of IVD records	
Sponsor and manufacturer must have an agreement to provide information to the TGA within 20 working days, upon request		
Reporting of adverse events.		

Sources

Links used within this document are prone to change. Please refer to the appropriate source for the most recent information. We endeavour to keep an up-to-date record of information at www.pharmout.net

PharmOut is an international GMP consultancy serving the Pharmaceutical, Medical Device and Veterinary industries. PharmOut specialises in PIC/S, WHO, United States FDA, European EMA, and Australian TGA GMP consulting, engineering, project management, training, validation, continuous improvement and regulatory services.

Our team includes international GMP experts who have previously held leadership roles within regulatory bodies.

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