Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

# IVD medical devices: Definitions & links

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Definitions of terms and links to other information about the regulation of IVDs.

## Definitions

The definitions provided below may be subject to some changes, depending on the final wording selected for legislative purposes.

### *in vitro* diagnostic device (IVD)

A medical device is an *in vitro* diagnostic medical device (IVD) if it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for *in vitro* use. It must be intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures.

The definition of an IVD does not encompass products that are intended for general laboratory use that are not manufactured, sold or presented for use specifically as an IVD.

### Medical Device

A medical device is defined in the legislation as any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related device (including any diagnostic product for *in vitro* use) that is intended by the manufacturer to be used, alone or in combination, for human beings for the specific purpose of one or more of the following:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

**Sponsor**

Section 3 of the *Therapeutic Goods Act 1989* defines a sponsor, in relation to therapeutic goods as:

a. a person who exports, or arranges the exportation of, the goods from Australia; or
b. a person who imports, or arranges the importation of, the goods into Australia; or
c. a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere);

but does not include a person who:

d. exports, imports or manufactures the goods; or
e. arranges the exportation, importation or manufacture of the goods;

on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.

**Manufacturer**

The manufacturer of a medical device is:

a. The person who accepts responsibility for the design, production, packaging and labelling of the device before it is supplied under the person's name; or
b. The person who, with a view to supplying the device under their name does one or more of the following to a ready made device:
    - Assembles the device,
    - Packages the device,
    - Processes the device,

- Undertakes refurbishment of the device,
- Labels the device, or
- Assigns to the device its purpose, by means of information supplied on or in any one or more of the following:
  - the labelling on the device;
  - the accompanying instructions for using the device;
  - any advertising material relating to the device;
  - technical documentation describing the mechanism of action of the device.

**Laboratory Network**

A laboratory organisation whose activities span more than one field of testing or program, or which operate at multiple sites within a field, or involve a combination of multiple sites and fields/programs under a single Approved Pathology Authority, with a single quality management system, is regarded as a Laboratory Network. Tests that are manufactured and distributed only within such a network are considered, for regulatory purposes to be manufactured "in-house".

- Such a laboratory network must have a quality policy common to all sites manufacturing and using the in-house tests.
- The quality system must be centrally managed and uniformly applied across all work locations manufacturing and using the in-house tests. Some local work instructions may be necessary due to location requirements etc. As a minimum requirement, the following elements of the quality system must be centrally managed:
  - Management review
  - Internal quality audits
  - Corrective and preventive action
  - Complaints
  - Changes to the quality system documentation for key elements
- The network must have procedures for the control of site calibration and/or testing
- The organisation must have appointed a management representative with responsibility for maintenance and application of the quality system across all sites, fields of testing and/or accreditation programs
- Laboratory organisations with appropriate NATA Corporate Accreditation can be considered as a laboratory network, and may manufacture and distribute within their network as manufacturers of in-house tests. Distribution of a laboratory manufactured test in a multi-site organisation that does not fulfil this definition will be considered as commercial supply, and these tests will be regulated as such.
- The laboratory network must operate under a single *Approved Pathology Authority* (APA).

**Serious Disease**

Serious diseases are those that result in death or long-term disability, which may be incurable or require major therapeutic interventions, and where an accurate diagnosis is vital to mitigate the public health impact of the condition.

**Kind of Medical Device**

Medical devices are considered to be of the same kind if they have the same sponsor, manufacturer, class and nomenclature code. One kind of medical device results in one inclusion on the Australian Register of Therapeutic Goods (ARTG).

**GMDN**

Global Medical Device Nomenclature. The Global Medical Device Nomenclature (GMDN) is a collection of internationally recognised terms used to accurately describe and catalogue medical devices, in particular, those products used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.

The GMDN is a classification system developed to allow the classification of all Medical Devices put onto the market.

**High Public Health Risk**

Refers to the high risk posed to the community in general by the propagation of infectious agents capable of causing life-threatening diseases. These diseases result in death or long-term disability, are often untreatable or require major therapeutic interventions. Accurate diagnosis/screening is vital to mitigate the public health impact of the condition.

**Low Public Health Risk**

Refers to the low risk posed to the community in general by infectious agents that are not easily propagated in a population or that are self-limiting diseases which rarely result in death or long-term disability.

**High Individual Risk**

Refers to the risk posed to an individual by an erroneous result. The impact of an erroneous result would place the patient in an imminent life-threatening situation or would have a major impact on outcome (death, severe disability, possible follow up measures) as it is critical or may even be the sole determinant for diagnosis. IVDs may result in a high level of risk to the individual because of stress and anxiety resulting from the information and nature of the possible follow-up measures.

**Moderate Individual Risk**

Refers to the risk posed to an individual by an erroneous result. These results are not the sole determinant of the condition, and if they are, it is not likely to result in death or severe disability, will not have a major impact on outcome or place the individual in immediate danger.

Top of page (#topofpage)

# Links

## Therapeutic Goods Administration

- Information about IVDs (https://www.tga.gov.au/node/287331)
- TGA eBusiness Services (DEAL and E-business with the TGA) (https://www.ebs.tga.gov.au)
- Public access to the ARTG (https://www.ebs.tga.gov.au/ebs/home.nsf/GHPR?Open&p=SearchARTGPublic)
- Recall information (https://www.tga.gov.au/node/287444) including the "Uniform Recall Procedure for Therapeutic Goods"
- Subscribe to updates from TGA (https://www.tga.gov.au/node/287392)

## Global Harmonisation Task Force

- Global Harmonisation Task Force (GHTF) (http://www.ghtf.org/)

## European regulation

- European Union in vitro diagnostic devices directive (IVDD) 98/79/EC (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0079:EN:HTML)
- List of recognized Notified Bodies under the European IVDD 98/79/EC (http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main)
- List of Harmonised IVD Standards for the IVDD 98/79/EC (https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en)

## GMDN

- GMDN (http://www.gmdnagency.com)

## National Notifiable Disease Surveillance System

- National Notifiable Disease Surveillance System (http://www.health.gov.au/internet/main/Publishing.nsf/Content/cda-surveil-nndss-nndssintro.htm)

## National Pathology Accreditation Advisory Committee

- National Pathology Accreditation Advisory Committee (http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-index.htm)

Top of page (#topofpage)

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**Topics:**

In Vitro Diagnostic medical devices (IVDs) (https://www.tga.gov.au/vitro-diagnostic-medical-devices-ivds)