



Australian Government

Department of Health
Therapeutic Goods Administration

The use of GMDN codes for IVD medical devices in Australia

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The GMDN is an international nomenclature system used by regional or national regulatory bodies to consistently describe medical devices¹. GMDN codes are used to assist in the:

- consistent assessment of devices before they are approved for supply
- ongoing monitoring of devices once they are available for supply.

The GMDN database is made up of a large number of generic device descriptors called preferred terms (PTs), each consisting of a term name, a definition and a unique 5 digit code that is used to identify a particular medical device. The preferred terms are arranged within the GMDN database so that they are grouped together based on similar characteristics, using a system of collective terms (CTs). The GMDN database is maintained by a not for profit agency based in the United Kingdom, with assistance from various technical experts around the world.

International regulatory authorities, including the TGA, liaise with the GMDN Agency to request amendments to existing codes and to create new codes. Other GMDN users may also make requests for new codes to the GMDN Agency. For more information please see the [GMDN Agency website \(http://www.gmdnagency.org\)](http://www.gmdnagency.org).

¹ The use of the term 'medical device' is taken to include 'IVD medical devices' - the latter term will be used to denote references that are specific to IVD medical devices.

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Category: Medical devices/IVDs

Tags: regulatory guidance, in vitro diagnostic medical devices (IVDs)

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