



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Medical Device Identification

Understanding the trends and developments

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TGA Health Safety
Regulation



Identification of medical devices

- **The Australian Register of Therapeutic Goods (ARTG)**
- **Risk classification of medical devices**
- **TGAs use of the GMDN**
- **Future trends**





Therapeutic Goods Administration

Oversees the safety and performance of medicines and medical devices supplied in Australia

Entry in Australian Register of Therapeutic Goods (ARTG) is the basis for legal supply

- *Therapeutic Goods Act, 1989*
- *Therapeutic Goods Regulations 1990*
- *Therapeutic Goods (Medical devices) Regulations, 2002*



ARTG product categories

- **Registered medicines**
 - Prescription (high risk) registered
 - Non-prescription (low risk) registered
- **Listed medicines**
 - Most over the counter medicines
- **Biologicals**
- **Medical Devices**
 - Includes IVDs since July 2010
- **Other therapeutic goods**
 - Registered
 - Listed
 - Exempt from entry in ARTG





Including medical devices in the ARTG

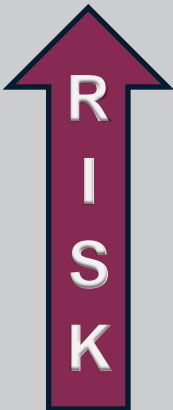
Sponsors apply to include the ‘same kind of medical device’ in the ARTG.

Medical devices are taken to be of the ‘same kind of medical device’ if they have:

- the same manufacturer; and
- the same sponsor; and
- **the same risk classification; and**
- **the same device nomenclature system code;**
- and for Class III, AIMD or Class 4 IVDs the same unique product identifier (UPI)



Classification of medical devices

	Medical Devices	In vitro diagnostic medical devices (IVDs)
	Class III/ AIMD	Class 4 IVDs
	Class IIb	Class 3 IVDs
	Class IIa	Class 2 IVDs
	Class I	Class 1 IVDs



Device nomenclature code (GMDN)

- The Global Medical Device Nomenclature (GMDN) is a comprehensive system of internationally recognised coded descriptors used to generically identify medical devices products.
- ISO 15225 - Medical device nomenclature data structure
- Use of the relevant GMDN code is prescribed in Australian legislation



Device nomenclature code (GMDN)

Preferred term

- the most specific term applied to a product for the purposes of identification

Collective term

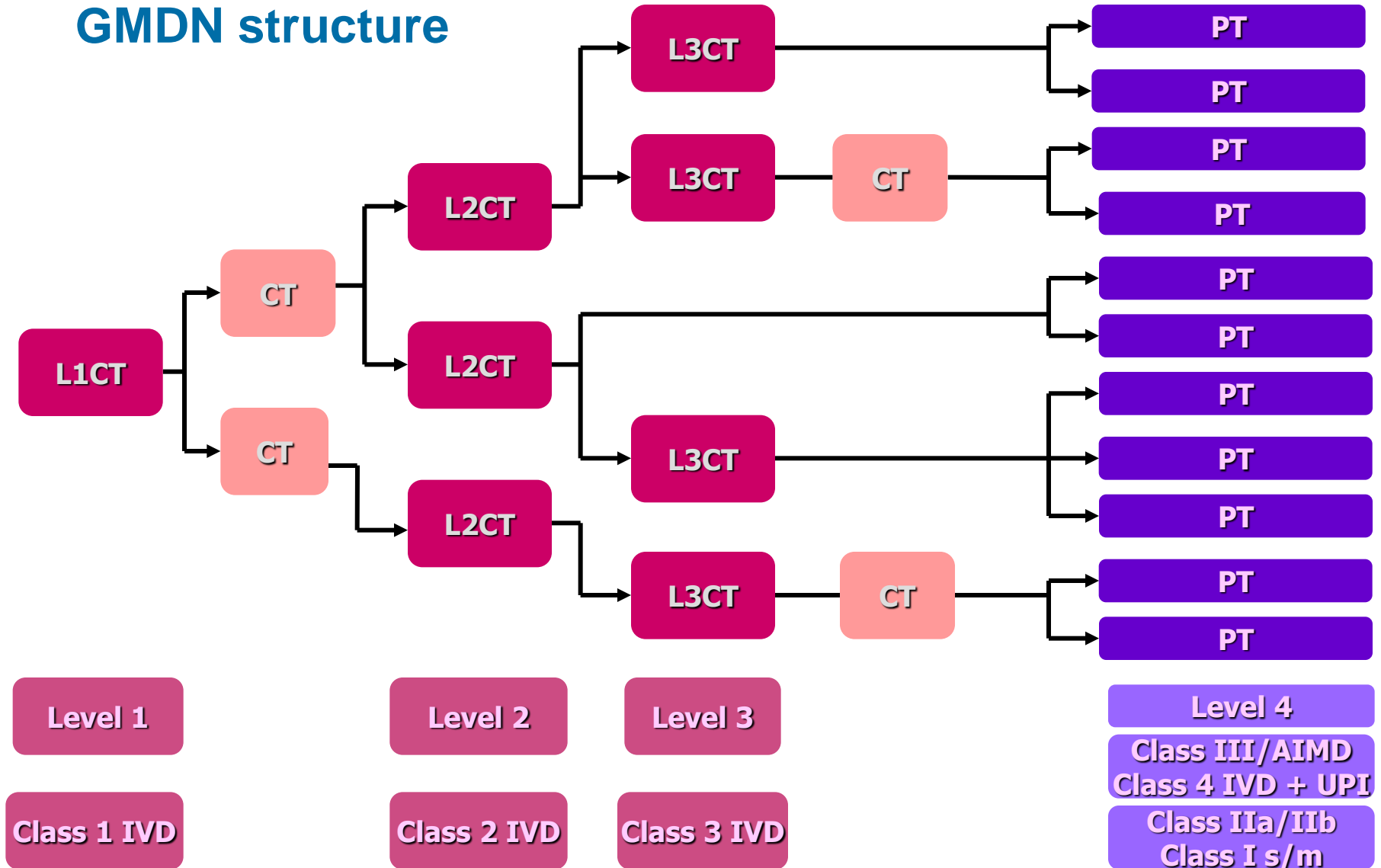
- groups together preferred terms based on their similar characteristics

Template term

- broad name used to group similar preferred terms and to develop a hierarchy in the nomenclature



GMDN structure





Device identification

- Random review of low risk medical devices applications
 - confirm intended purpose and specified GMDN term consistent with entry in ARTG as a Class I medical device
- Targeted reviews or regulatory investigations
 - GMDN codes used to identify/search ARTG for investigation
- National Product Catalogue
- Fields from ARTG align with the NPC
 - ARTG number and category (Registered, Listed, Included etc)
 - Sponsor name
 - GMDN code
 - Risk classification



Into the future

- Availability of individual product names approved for supply in Australia
- Australian implementation of UDI
 - International Medical Device Regulators Forum (IMDRF)



<http://www.tga.gov.au>