Definitions

Term	Definition
Australian Register of Therapeutic Goods (ARTG)	This is the public database of therapeutic goods that can be legally supplied in Australia. It is maintained under section 9A of the *Therapeutic Goods Act 1989* for the purpose of compiling information in relation to, and evaluation of, therapeutic goods for use in humans.
Active implantable medical device (AIMD)	This is an active medical device intended to be partially or completely implanted (medically or surgically) into the body, where it is meant to stay for an extended amount of time. An active medical device is a device that relies on electrical energy or a power source that is different to what is generated by the human body or gravity in order to function. These devices may be implanted for diagnostic or therapeutic purposes. Since they are meant to remain in the body for extended amounts of time, they must meet rigorous requirements and standards to ensure patient health and safety. All AIMDs are classed as high risk (Class III) medical devices and include devices such as pacemakers, implantable defibrillators, cochlear implants and neurostimulators.
Adaptable medical device	A mass-produced medical device that is intended by the manufacturer to be assembled, adjusted, shaped, or adapted after it has been supplied, in accordance with the manufacturer's instructions, to: (a) address either or both anatomical and physiological features of a particular individual, or (b) address a pathological condition of a particular individual, or (c) otherwise perform as intended by the manufacturer. Adaptable medical devices may be exempt from Australian Register of Therapeutic Goods (ARTG) requirements at point of care. (See "point of care manufacturing".
Adverse event (AE)	Unintended and sometimes harmful occurrences associated with the use of a medicine, vaccine or medical device (collectively known as therapeutic goods). Adverse events include side effects to medicines and vaccines, and problems or incidents involving medical devices. In the case of medical devices, an adverse event can also be a problem or incident that has caused, or could cause, harm to patients, caregivers, healthcare professionals or others. These can include "near misses"; these are events that might have led to a death or serious injury. It may be that timely intervention from a healthcare professional prevented an adverse event. Importantly, an adverse event is not always caused by the therapeutic good itself. An adverse event could be a result of incorrect use of the device, or other circumstances such as two properly functioning devices that do not operate as intended when used in combination. The occurrence of an adverse event does not necessarily mean that there is something wrong with the therapeutic good.
Agent	Any consultant, corporation or other organisation or person who is duly appointed by the sponsor or Australian manufacturer to represent them in consultations with the Therapeutic Goods Administration (TGA). The agent cannot be a member of the sponsor/manufacturer, nor their client base. Agent **does not** mean a sponsor who is the "Australian Agent"/distributor of an overseas manufacturer.

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Australian Unique Device Identification Database (AusUDID)	A public facing searchable database that will enable timely access to complete, accurate and consistent information about medical devices. The introduction of the UDI system in Australia will support the development of AusUDID.
Authorised Prescriber	To access an unapproved product for multiple patients, you can become an Authorised Prescriber. To prescribe biologicals or medical devices, use the standard pathway. These products are not on the established history of use list. As an Authorised Prescriber, you can access an unapproved product for a particular indication. You will not need to seek approval for each individual patient. You must report: •any suspected adverse event or product defect •how many patients you have treated every 6 months. (See "Special Access Scheme" and "Unapproved therapeutic goods")
Base Unit of Measure (BUoM)	This is the unit of measure in which the stocks of a material are managed. In NSW Health, this is also known as the Primary Unit of Measure (PUoM). The Oracle system used in NSW Health converts all quantities entered in other units to the BUoM (this definition has been adapted from the System Analysis Program Enterprise Resource Planning data dictionary).
Class I medical device	Low risk medical devices present the lowest risk with minimal potential for harm. They are considered to have a very low safety risk to consumers (for example, surgical retractors and tongue depressors) do not require conformity assessment certification before they can be included in the Australian Register of Therapeutic Goods (ARTG). They are included in the ARTG on the manufacturer's declaration that the devices comply with the relevant essential principles for safety and performance.
Class Im (Measuring) medical device	A low to medium risk medical device with a measuring function. This class is exempt from the UDI requirements. Examples are an oral syringe, surgical drill guide and ECG recording paper.
Class Is (Sterile) medical device	A low to medium risk medical device that is supplied sterile. This class requires a UDI; for example, surgical gown, sterile glove, medical drape equipment and basic IV set.
Class IIa medical device	A low to medium risk medical device (for example, intra venous (IV) tubing, dental drills, ultrasound machines, and digital and infrared thermometers).
Class IIb medical device	A medium to high-risk medical device (for example, electrosurgical electrodes, lung ventilators, surgical laser, and diagnostic x-ray).
Class III medical device	A high-risk medical device (for example, prosthetic heart valves, absorbable surgical sutures, hip prostheses, and pacemakers).
Client	A person or organisation that is involved in the import, export, manufacture, or supply of therapeutic goods. An enterprise can include sponsors, manufacturers, and agents.
Client ID	This is the identification code assigned by the Therapeutic Goods Administration (TGA) to a client.
Conformity assessment	This is the systematic and ongoing examination of evidence and procedures for medical device manufacturers use to ensure that a medical device (including an IVD medical device) complies with the quality manufacturing systems and undergoes appropriate product assessment, which could include the "Essential Principles".

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Custom-made medical device (CMMD)	A medical device that: (a) is intended by the manufacturer to be for: (i) the sole use of a particular patient (the intended recipient), or (ii) the sole use of a particular health professional (the intended recipient) in the course of the health professional's practice; and (b) is manufactured by the manufacturer in accordance with a written request of a health professional (the requesting health professional) and with particular design characteristics specified by that health professional in the request (even if the design is developed in consultation with the manufacturer), where those design characteristics are intended to address: (i) either or both of the anatomical and physiological features of the intended recipient, or (ii) a pathological condition of the intended recipient; and (c) the requesting health professional has determined is necessary to address the matters covered by paragraph (b) because there is no kind of medical device included in the Register to address those matters or to address those matters to an appropriate level (d) reduced scope and almost non-existent (e) exempt from TGA approval and ARTG inclusion.
Defect (medical device/product)	1. Product defect refers to the deviation of a distributed product from the standards specified in the approved application, or any significant chemical, physical, or other change, or deterioration in the distributed product. 2. Concern about the quality, authenticity, performance, or safety of any medication or device.
Essential Principles	These are safety and performance requirements for medical devices, including in vitro diagnostic (IVD) devices. They set out the requirements relating to the safety and performance characteristics of medical devices. They are used for medical devices Class I and may inform part of the Conformity Assessment for Class II and Class III.
Excluded goods	Products excluded from regulation (under the Excluded Goods Order 2018) do not need to be included in the Australian Register of Therapeutic Goods (ARTG) before they can be exported from, imported to, or supplied within Australia. Some examples of excluded goods include: •adhesive removers and non-medicated skin cleansers •antiperspirant preparations that derive their antiperspirant properties from inorganic salts •dental bleaches and dental whiteners •household detergents and soaps for laundering or general cleaning use •hair bleaches and hair dyes •mouthguards intended by the manufacturer to be used to protect teeth from external forces including, but not limited to, mouthguards used in contact sports, spectacle frames.
Exempt goods	Therapeutic goods that fall under the oversight of the Therapeutic Goods Administration (TGA) but with exemptions from meeting certain legal requirements. For some medical devices, it could mean exemption from registering in the Australian Register of Therapeutic Goods (ARTG).

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Global Medical Device Nomenclature (GMDN) code	1. 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. 2. The unique five-digit code assigned to the device by the manufacturer.
Global Trade Item Number (GTIN)	This is a number that can be used by a company to uniquely identify all its trade items. It is the number found in the barcode. GS1 defines trade items as products or services that are priced, ordered or invoiced at any point in the supply chain. The GTIN can be used to identify types of products at any packaging level (for example, consumer unit, inner pack, case, and pallet). Groups of trade items with similar production and usage characteristics such as production batches can be further identified with the help of the batch/lot number, expiry date, and similar data elements. Individual trade items can be uniquely identified using a GTIN and serial number.
Good manufacturing practice (GMP)	GMP is used internationally to describe a set of principles and procedures which, when followed by manufacturers of therapeutic goods, helps ensure that the products manufactured will have the required quality. A basic tenet of GMP is that quality cannot be tested into a batch of product but must be built into each batch of product during all stages of the manufacturing process.
Health Level 7 (HL7)	This is a Structured Product Label (SPL). Health Level 7 (HL7) International is an international standards development organisation that provides a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services globally. HL7 Australia is HL7 International's affiliate.
High risk medical device	These are Class IIb and Class III medical devices that are considered to have the highest risk. These high-risk medical devices usually sustain or support life, are implanted, or present a potential unreasonable risk of illness or injury, such as pacemakers.
Implantable medical device (IMD)	This is a medical device (other than an active implantable medical device) that is intended by the manufacturer: •to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure, or •to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure, or •to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure.
ims+	The NSW Health online incident management system used to record and report incidents by NSW Health staff and services. These incidents may include sentinel events, adverse events and near misses.
Incident	An unplanned event that results in, or has the potential for, injury, damage, or loss, including near-misses. An incident may also be referred to as an "adverse event".

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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.
Intended purpose	In relation to a medical device, this means the purpose for which the manufacturer of the device intends it to be used, as stated in: (a) the information provided with the device (b) the instructions for use of the device, or (c) any advertising material applying to the device.
"Kind" of medical device	Devices are taken to be of the same kind if they have the following characteristics: (a) the same Sponsor (b) the same Manufacturer (c) the same Classification (d) the same Global Medical Device Nomenclature System code (GMDN code) (e) for Class III, Class AIMD medical devices and Class 4 IVD medical devices (other than an immunohaematology reagent that is a Class 4 IVD medical device) the same unique product identifier (UPI).
Label	Means a display of printed information: •on or attached to the goods, or •on or attached to a container or primary pack in which the goods are supplied, or •supplied with such a container or pack.
Low risk medical device	These are usually Class I medical devices, such as surgical gloves and tongue depressors. They may not present a potential unreasonable risk of illness or injury to consumers.
Manufacturer	The manufacturer of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations. Manufacturers take full responsibility for the design and production of a medical device, whether they make the device themselves or subcontract some of these activities. The name and address of the manufacturer must be provided on the device label. Also, the manufacturer has the following responsibilities: • defines the intended purpose of the device • ensures the device meets the Essential Principles • applies for, and maintains, Conformity Assessment Certification/Submits the Declaration of Conformity (Class 1 only) • notifies the Therapeutic Goods Administration (TGA) when "substantial changes" to quality management system, product design or information provided with devices occur.

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Medical device	Any instrument, apparatus, appliance, software, implant, reagent, material, or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: (i) diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease (ii) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability (iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state (iv) control or support of conception (v) in vitro examination of a specimen derived from the human body for a specific medical purpose.
Medical Device Production System (MDPS)	A system that consists of raw materials and main production equipment (whether or not the system also consists of software), where the system is intended by the manufacturer to be used (whether or not with ancillary inputs or equipment) by a health professional, or suitably qualified person within a healthcare facility, to produce a particular medical device for use in relation to a patient of the health professional or healthcare facility.
Medical Devices Vigilance Program (MDVP)	An initiative of the Therapeutic Goods Administration (TGA) to improve sponsors' understanding of, and compliance with, their post-market vigilance regulatory requirements, through a self-assessment tool and program of desktop audits and on-site inspections. The MDVP was developed following the 2020 TGA consultation titled, "Proposed enhancements to adverse event reporting for medical devices".
Near-miss	An unplanned event that did not result in injury, illness or damage but had the potential to do so. A break in the chain of events prevented harm, due to recognition and action staff or an unexpected event.
Off-label use	This generally refers to the use of a therapeutic good for an indication or intended purpose that is not specified in its Australian Register of Therapeutic Goods (ARTG) entry. Therapeutic goods are included in the ARTG with either specific indication(s) or intended purpose(s). The *Therapeutic Goods Act 1989* does not regulate clinical practice. "Off-label use" is a clinical decision made at the discretion of the treating clinician who is responsible for obtaining informed consent from their patient and ensuring that the medical device is the appropriate treatment option and carries a positive benefit-risk profile.
Patient Implant Card (PIC)	This is used to record the details of the specific device that the patient had implanted. The details include device name and model, the devices UDI, batch code, lot number, and/or serial number, and the manufacturer's contact details. It may also include the implanting doctors' details.
Patient information leaflet (PIL)	This is information to inform patient discussions and the decision to implant a type of medical device.

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Patient-matched medical device (PMMD)	This is a medical device that: (a) is manufactured by the manufacturer, within a specified design envelope, to match: (i) either or both of the anatomical and physiological features of a particular individual, or (ii) a pathological condition of a particular individual; and (b) is designed by the manufacturer (even if the design is developed in consultation with a health professional); and (c) is manufactured using production processes that are capable of being: (iii) either or both validated and verified; and (iv) reproduced.
Personalised medical device (PMD)	A device that is specifically designed and manufactured, or adapted/modified, to meet the needs of an individual. The Therapeutic Goods Administration (TGA) uses three specific terms to describe personalised medical devices, as follows: 1. patient-matched medical devices 2. adaptable medical devices 3. custom-made medical devices.
Point of care (PoC) manufacturing	Healthcare facilities in Australia are developing point of care manufacturing capabilities using methods such as 3D printing to produce a wide variety of medical devices. PoC manufacturing regulations apply to those people (such as healthcare professionals) manufacturing these medical devices, in both public and private settings.
Primary DI Issuing Agency	This is the Issuing Agency that provided the primary device identifier. Issuing Agencies are organisations approved to manage UDI format and structures according to international standards, and issue those to medical device manufacturers. The TGA will support the three Issuing Agencies that are currently common to the US and EU, as follows: •Global Standards One (GS1) • Health Industry Business Communications Council (HIBCC) • International Council for Commonality in Blood Banking Automation (ICCBBA).
Primary Unit of Measure (PUoM)	See Base Unit of Measure (BUoM).
Quality Audit Reporting System (QARS)	This is an electronic tool developed by the Clinical Excellence Commission (CEC) to help to improve the quality and safety of healthcare provided by local health districts, speciality health networks, pillars and NSW Health service providers ("the Health Entities"). The QARS application has three modules including Audit, Survey and ReACT.
Quality Management System (QMS)	A set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organisation. A QMS is required as part of a Conformity Assessment.
SmartChain	This is a statewide digital solution for NSW Health procurement and supply chain and is part of the NSW Health Procurement Reform work.

Definitions

SmartChain Traceability	The SmartChain Traceability solution is a NSW Health end-to-end tracking solution that manages the supply of implantable devices and other products across the supply chain. The solution can quickly track items to patients, improving stock management, and enhancing ordering and reporting capabilities. It also reduces the risks of adverse patient safety outcomes in the event of product recalls.
Special Access Scheme (SAS)	The Therapeutic Goods Administration (TGA) encourages the use of therapeutic goods that are included in the Australian Register of Therapeutic Goods (ARTG). However, there are times when patients require therapeutic goods that are not included in the ARTG. The SAS allows Australian-registered health practitioners to access an "unapproved" therapeutic good for an individual patient on a case-by-case basis. If you are a medical practitioner wanting to prescribe an unapproved therapeutic good to multiple patients (a class of patients) on an ongoing basis, you should consider becoming an Authorised Prescriber.
Sponsor	Someone who sends/brings/organises medical devices in Australia. However, a sponsor cannot be someone who does these actions on behalf of another person or business that is based in Australia. In Australia, therapeutic goods must be included on the Australian Register of Therapeutic Goods (ARTG) before they can be sold. The sponsor is responsible for applying to the Therapeutic Goods Administration (TGA) to have their therapeutic good included on the ARTG and also responsible for the following: • meeting advertising requirements • reporting adverse events • maintaining records of supply • submitting a Device Change Request form if the ARTG listing becomes outdated (or if otherwise requested to do so by the TGA). If the sponsor is also the manufacturer they carry the responsibilities of the manufacturer.
Substantial change	This is a change to the manufacturer's Quality Management System (QMS) or medical devices, including in vitro diagnostic (IVD) medical devices, that are expected to impact the quality, safety or performance of the devices. The concept of a substantial change is linked to the principles of safety and performance in the context of a risk-based regulatory framework to control the risk of medical devices.
Surgical mesh	This is used in the repair of soft tissue, or mixed soft tissue/bony structural defects, to support organs and/or tissues or to strengthen the integrity of a body cavity. Surgical mesh is implanted in the body for repair or reinforcement and includes tapes and slings. Surgical mesh includes the range of devices classified as: (a) synthetic surgical mesh used for breast implant surgeries (b) surgical mesh used to treat male stress urinary incontinence (c) surgical support tape, non-absorbable (tissue approximation, ligaments, tendons or other soft tissues) (d) surgical support tape, non-absorbable (reinforcement of the tendon). All surgical meshes are considered high risk and are Class III medical devices.

Definitions

Traceability	This is the ability to trace the history, location or status of a medical device through its entire life cycle. In reference to the TGA's medical device reforms, this is the "shelf-to-patient" journey of the medical device. By being able to trace the history of a product, it is possible to quickly identify and recall products that may be contaminated or defective.
Trackability	This is the ability to track a medical device from production/procurement to purchasing facility. This is the "procure-to-pay" journey of the medical device. Trackability is at the start of the traceability process but does not include information to patient. By being able to track the journey of a product, it is possible to quickly identify and recall products in facilities that may be defective.
Unapproved therapeutic goods	Products that are not included in the Australian Register of Therapeutic Goods (ARTG) are referred to as unapproved therapeutic goods. Unapproved therapeutic goods have not been evaluated for their quality, safety or effectiveness by the Therapeutic Goods Administration (TGA). Clinicians are able to prescribe unapproved products when there is clinical justification which meet TGA criteria outlined by: •an individual patient on a case-by-case basis - Special Access Scheme (SAS) •multiple patients with the same condition - Authorised Prescriber (AP).
Unique Device Identifier (UDI)	The UDI system is a series of alphanumeric or numeric characters that is based on globally accepted coding standard and is applied to a specific medical device model, including implants. The UDI system will improve medical device identification, trackability and traceability. The model of medical device which is used as the “access key” to information stored in the Australian UDI database (AusUDID) and will be used for device related information such as adverse events and recalls. The UDI is made up of two components: Unique Device Identifier - Device Identifier (UDI-DI) and Unique Device Identifier - Production Identifier (UDI-PI).
Unique Device Identifier - Device Identifier (UDI-DI)	This is the fixed, static portion of the UDI. The DI identifies the manufacturer and the specific model or version of the device. The primary DI is the main lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use.
Unique Device Identifier - Production Number (UDI-PI)	This is the dynamic portion of the UDI that identifies lot, serial or batch number, expiration date and manufacture date. The UDI-PI is on the device and/or labelling but not stored in the AusUDID.
Unit of Issue (UoI)	This is a unit of measure in which the material is issued from the warehouse. It allows consumption, stock transfers, transfer postings and physical inventories to be recorded in a unit differing from the base unit of measure and from the stockkeeping unit (definition has been adapted from System Analysis Program Enterprise Resource Planning data dictionary).
Unit of Purchase (UoP)	When purchasing materials, UoP is the multiple of individual items in which the purchase is expressed. For example, if hand towels are packed in sleeves of 50 and there are 20 sleeves in a box, the UoP could be a single hand towel, a sleeve of 50 or a box of 1,000 (adapted from Supply Chain Management Portal website, as defined by Chartered Institute of Procurement and Supply (CIPS-UK)).

Unit of Use (UoU)	A virtual identifier assigned to an individual medical device when a Unique Device Identifier (UDI) is not labelled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient when a base package contains more than one device (definition has been adapted from the US Food and Drug Administration).
Wires	Wires are considered to be singular continuous pieces of metal (identical to everyday wire) used to reattach bone fragments or provide stability. Wires are exempted from the need to provide patient information. Wires must not be confused with leads (for example, pacing leads).