Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Examples of boundary and combination products and their product category

Version 2.0, April 2024

Contents

Category

Below is a list of some boundary and combination products and the most appropriate regulatory category likely applicable. The list includes products intended for **therapeutic use only**. Information provided below must be read in conjunction with the guidance on Boundary and combination products.

Updates to the list

This document will be updated to include further products and clarification as required. Discussions are underway about the regulation of head and body lice products, moisturisers and emollients, and toothpastes. The document will be updated once a decision has been finalised.

Product	Product category	Rationale
Absorbable, with shape, used in surgery		
Tissue adhesives (may include cyanoacrylates, fibrin-based adhesives)	Medical Device	Principal intended action is primarily achieved by physical means even though they may attach by chemically crosslinking to tissues, which is ancillary action.
Absorbable, without shape, used in surgery		
Visco-elastic fluids such as intra-ocular visco-elastic fluids and synovial (animal origin) visco-elastic fluids	Medical Device	Act by physical means to protect tissues from trauma by providing lubrication, cushioning, and maintaining space between tissues. Absorption by metabolic means is ancillary action.
Absorbable implants		
Collagen injections	Medical Device	Principal intended action of smoothing out wrinkles achieved by adding volume, absorbing water, and providing structural support. Resorption of the filler by metabolic means is ancillary action.
Hyaluronic acid injections (when used as filler or lubricant)	Medical Device	
Skin mesh products derived from human tissue such as collagen cell-free extracellular matrices	Biological	As per section 32A (1)(a)(i) of the *Therapeutic Goods Act 1989* (the Act)
Antiseptics, disinfectants, cleaners, soaking solutions		
For use on skin		
Antiseptic 'wipe' or sponge	Medicine	For products containing antiseptics, the targeting and killing of micro-organisms is achieved through pharmacological action and regulated as medicine.
Moist swab (with antiseptic claim)	Medicine	
Moist swab (with no claims other than cleaning the skin)	Medical Device	

Product	Product category	Rationale
Fabric dressing with antiseptic (unless primary intended action is to deliver the antiseptic)	Medical Device	Those products without an antiseptic claim achieve their principal intended action through physical means and regulated as medical device. See Disinfectants, sterilants and sanitary products
Antibacterial hand sanitisers	Medicine	Antibacterial hand hygiene products that claim to kill specific organisms and/or are to be used in hospital settings. For more information see Hand sanitisers: Information for manufacturers, suppliers and advertisers.
Hand sanitisers that meet the requirements of the specified excluded goods determination	Excluded	As per the Therapeutic Goods (Excluded Goods-Hand Sanitisers) Determination 2020.
For use on inanimate objects (hard or soft surfaces)		
Hospital grade or household/ commercial grade disinfectant that do not make specific claims*	Other therapeutic good (exempt)	See Disinfectants, sterilants and sanitary products * Virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity are known as "specific claims". More information can be found in the Disinfectant Claim Guide.
Hospital grade or household/ commercial grade disinfectant that make specific claims* to kill microorganisms	Other therapeutic good (listed)	See Disinfectants, sterilants and sanitary products
Disinfectant and sterilant gases	Excluded	As per Schedule 1, Item 5 of the Therapeutic Goods (Excluded Goods) Determination 2018
Ostomy appliance detergents, deodorisers	Excluded	As per Schedule 1, Item 1 of the Therapeutic Goods (Excluded Goods) Determination 2018
Body 'cleaning' and irrigation substances		
Bulk forming laxatives (including ispaghula husk and methylcellulose)	Medicine	Hydrophilic function by chemically attracting and sequestering extra water in stools.

Product	Product category	Rationale
Osmotic laxatives (including lactulose and polyethylene glycol)	Medicine	Soften stools by osmotically increasing the amount of water in the intestinal lumen by pharmacological or metabolic means.
Gastrointestinal detoxifier	Medicine	Chelating compound that acts through metabolic effect in the gut.
Enema solutions for rectal administration of medicine	Medicine	Principal intended action is primarily achieved by pharmacological or metabolic means of the medicine. Actions achieved by physical means (for example, water pressure) are ancillary actions.
Douches, including kits for therapeutic use	Medical Device	Physically remove debris using water-based solutions. See System or Procedure Packs.
Unmedicated, physiological solutions for irrigation such as pre-filled saline syringe - catheter, flush syringe, eye irrigation solution, isotonic saline for nasal irrigation)	Medical Device	Principal intended action of irrigation is achieved by physical means (mechanical rinsing), even if there are additives in the solution that are not medicines with ancillary action for example, preservatives.
Solutions for irrigation that incorporate active ingredient, such as substances with an antimicrobial action	Medicine	Products containing medicinal substance, achieving the principal intended action primarily by pharmacological or metabolic means, for example killing microorganisms and reducing infection risk. The solution is for delivering the medicine and considered ancillary action.
Activated charcoal used internally	Medicine	Principal intended action is achieved by metabolic means and regulated as medicine.
Hypertonic saline for inhalation	Medicine	Inhaled hypertonic saline increases mucus clearance by osmotically increasing water content and disrupting ionic bonds in mucus. The principal intended action is not through physical means.
Hypertonic eye drops	Medicine	Hypertonic eye drops reduce swelling in the eye by osmotically drawing out water.

Product	Product category	Rationale
Body fluid replacements and nutrients		
Blood substitutes and plasma expanders	Medicine	These are of two main types: • Crystalloids (such as saline solution) increase both intravascular and interstitial blood volume by decreasing osmotic pressure. • Colloids contain larger insoluble molecules that exert osmotic pressure which draws fluids inward, to increases blood volume.
Peritoneal dialysis solutions and substances prepacked for their preparation	Medicine	Works primarily by altering the concentration of chemical and biological substance within the body and regulated as medicine.
Haemofiltration solutions	Medicine	Works primarily by altering the concentration of chemical and biological substance within the body and regulated as medicine.
Haemodialysis solutions not in direct contact with blood that is, other side of membrane (in-vitro)	Medical Device	Concentrates for haemodialysis that are not intended to be used in direct contact with the blood are regulated as medical device.
Apheresis solutions	Medical Device	Non-invasive product with principal intended action primarily achieved through physical means such as physical separation.
Contact lens care products		
Contact lens cleaning, disinfecting, rinsing or hydrating solutions	Medical Device	Products specifically to be used for disinfecting, cleaning, rinsing or hydrating contact lenses are specified as medical devices as per Schedule 1, Item 5 of the Therapeutic Goods (Medical Devices - Specified Articles) Instrument 2020.
Wetting agents	Medical Device	
Hydrating agents	Medical Device	
Comfort drops	Medical Device	
Soft contact lens lubricants	Medical Device	
Hard contact lens lubricants	Medical Device	
Diagnostic imaging or similar agents		
Diagnostic imaging or similar agents (in vivo) for use in conjunction with: • Positron emission tomography	Medicine	In vivo imaging agents injected, ingested, or otherwise instilled into the body are declared to not be medical devices as per Schedule 1,

Product	Product category	Rationale
• Computerised axial tomography • Nuclear magnetic resonance imaging • Ultrasonography • X-ray imaging • Radionucleotide scanning		Item 6 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.
Agents injected, ingested, or otherwise instilled into or applied to the body for use in device therapy, such as in vivo imaging agents: • laser fluorescent dyes • fluorescein ocular drops/strips • injectable fluorescein • laser/UV light activated agents • lithotripsy imaging agents	Medicine	
Dyes or markers used to identify or to mark normal anatomy (for example, surgical marker pen to mark planned incision, identification of normal anatomy of the eye)	Medical Device	Dyes and stains (that do not contain a medicine) for identification of normal anatomy are regulated as medical devices.
Dyes used to identify damaged, or tissue affected by pathological processes (for example, dye or tracer used for sentinel node biopsy, dye used to identify corneal abrasion)	Medicine	Dyes and stains used to identify damaged tissue affected by pathological processes (diagnostic purposes) are considered medicines. For example, dyes used for identification of a corneal lesion or a sentinel lymph node.
In vitro diagnostic (IVD) goods		
That incorporate material of human origin	Medical Device	IVD medical devices and in-house IVD medical devices are specified to not be biologicals as per Schedule 2, Item 3 of the Therapeutic Goods (Biologicals - Specified Things) Instrument 2021. See guidance on IVDs
Breath test for *Helicobacter pylori* co-packaged with labelled urea	Medical Device	
Diagnostic goods for in vivo use		
Labelled urea for *Helicobacter pylori* test	Medicine	Principal intended action is achieved by immunological, pharmacological or metabolic means.
Allergen skin tests such as scratch test and patch test	Medicine	

Product	Product category	Rationale
Tartaric acid for testing patient reflex cough	Medicine	Products may contain a device component, but the action is ancillary as the device components are used for delivering or applying the medicine. These are not IVD medical devices as the test sample is not taken out of the body
External use products (for therapeutic use only) A product without intended therapeutic use is not a therapeutic good.		
Emollient and moisturising preparations	Medical Device	Principal therapeutic action is through providing a protective barrier from the external environment to keep moisture in or out and has a therapeutic intended purpose.
Emollient and moisturising preparations containing an active ingredient	Medicine	The product is intended to treat skin irritation or lesions through pharmacological, metabolic, or chemical means.
Skin adhesive and adhesive enhancers	Medical Device	Holds products against the skin using physical force, even though they may attach by crosslinking chemically.
Extra-corporeal therapies		
Immunoadsorption columns including charcoal activated and those using monoclonal antibodies	Medical Device	Principal intended action is primarily achieved through physical means such as adsorption and physical separation.
Haemoperfusion columns	Medical Device	Principal intended action is achieved through physical means such as adsorption and physical separation.
Anticoagulant used on human blood that is in continuous circulation with the body	Medicine	Principal intended action is primarily through pharmacological or metabolic means.
Perfusion circuit with heparin	Medical Device	Principal intended action is achieved through physical means and heparin results in ancillary action.
Hard-tissue scaffolds		
Hard-tissue scaffolds that primarily act by physical means such as hydroxyapatite (with or without collagen), calcium phosphate (with or without collagen), coral, bioglass, and cartilage repair systems	Medical Device	Principal intended action is achieved through structural support for subsequent tissue grown and repair.

Product	Product category	Rationale
incorporating non-human derived tissue		
Cartilage repair systems incorporating human tissue	Biological	The product has tissues derived from humans and is regulated as per section 32A (1)(a)(i) of the Act.
Haemostatic agents		
Haemostatic agents that primarily act by physical means (for example, collagen, cellulose, gelatines, polysaccharides, matrices, sealants, and adhesives)	Medical Device	Principal intended action is primarily achieved by physical means through: • Absorbing water from blood, • Forming a matrix structure to allow/promote platelet aggregation, and • Adhering to tissue or bone to form physical barrier blocking blood flow. Collagen can also activate platelets by pharmacological means, this is considered ancillary action.
Haemostatic agents that primarily act by augmenting the coagulation cascade (for example, thrombin and fibrin sealants)	Medicine	• Thrombin chemically converts soluble fibrinogen in blood plasma into insoluble fibrin in response to triggers such as vessel wall injury. • Fibrin sealant is formulation of human thrombin, human fibrinogen and antifibrinolytic inhibitor that delays clot degradation (synthetic aprotinin) which upon mixing, mimics a physiological clot. See Multi-component packs
Gingival retraction cords coated with adrenalin or astringent	Medical Device	Principal intended action of retracting tissue is achieved by the cord; added components aid this effect therefore have an ancillary effect.
Dentistry products with aluminium chloride used for haemostasis	Medical Device	Principal intended action is primarily achieved through physical effect on the protein coagulation and are regulated as medical device.
Lubricants and gels		
Electrode gels	Medical Device	Principal intended action is achieved through physical means by reducing

Product	Product category	Rationale
		electrical resistance and by conducting the signal for diagnostics such as Electroencephalogram (EEG), Electrocardiogram (ECG) and Electrophysiology (EP) examinations.
Lubricants represented for therapeutic use	Medical Device	Principal intended action of reducing damage due to friction is achieved through physical means. For example, substances intended to facilitate the passage of a medical device within the human body or between bodily structures, such as the surfaces of a joint or between eyelid and eyeball or to lubricate the surface of the eye.
Lubricants with spermicide/virucide	Medicine	Principal intended action is achieved by the spermicide/virucide through pharmacological means. Lubricant is used as a delivery mechanism.
Vaginal gel such as those that maintain Potential of hydrogen (pH) balance	Medicine	Principal intended action is metabolic, altering the chemistry of a part of the body.
Artificial tears for use with/without contact lenses (unmedicated)	Medical Device	Act by physically protecting the eye through lubrication. Absorption by the body through metabolic means is ancillary action.
Artificial saliva	Medical Device	Principal intended action is by physically providing lubrication to moisten and prevent mechanical trauma.
Medical gases		
Oxygen and other medical gases (except cryogenic gases, gases for mechanical use, and sterilant gases)	Medicine	See Medicinal gases guidance
Sterilant gases	Excluded	Disinfectant and sterilant gases are excluded as per Schedule 1, Item 5 of the Therapeutic Goods (Excluded Goods) Determination 2018.
Oxygen – chemical generators	Medicine	Declared to not be medical devices as per Schedule 1, Item 4 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.

Product	Product category	Rationale
Gas used as a diagnostic such as gas mixtures for pulmonary function testing devices	Medicine	In vivo imaging agents injected, ingested, or otherwise instilled into the body are declared to not be medical devices as per Schedule 1, Item 6 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.
Oxygen concentrators	Medical Device	It is an apparatus that increases the concentration of oxygen by physical means.
Gases for mechanical use on humans (e.g., to expand a body cavity or create a tamponade)	Medical Device	Insufflation gases for the abdominal cavity or laparoscopic and endoscopic procedures intended exclusively for minimal access surgery with a physical mode of action (e.g., inflation).
Compressed gases when used as a power source for a medical device	Excluded	As per Schedule 2, Item 4 of the Therapeutic Goods (Excluded Goods) Determination 2018.
Multi-component packs Comprises of kits, composite packs, system or procedure packs and surgical loan kits. Kits and composite packs are defined under section 7B, and System or procedure packs contain medical devices are defined under section 41BF of the Act. Composite packs and kits do not contain medical devices. Refer to guidance on system or procedure packs and multi-component packs for more information.		
Composite pack containing medicine	Medicine	Composite packs containing medicine are regulated as medicine, even if they contain biologicals.
Composite pack not containing medicine (biologicals only)	Biological	Composite packs containing biologicals only (no medicine) are regulated as biologicals.
Kits containing medicine	Medicine	Kits containing medicine are regulated as medicine, even if they contain biologicals.
Kits not containing medicine (biologicals only)	Biological	Composite packs containing biologicals only (no medicine) are regulated as biologicals.
System or procedure packs (SOPPs)	Medical Device	SOPPs must include a medical device or an in vitro diagnostic (IVD) medical device and depending on its intended purpose may also include medicine, biologicals, other therapeutic goods or

Product	Product category	Rationale
		goods that are not considered to be therapeutic goods. First aid kits are also regulated as SOPPs as they include device components.
Surgical loan kit	Medical Device (Exempt)	Surgical loan kits are not SOPPs. They ONLY contain medical devices. All goods in a surgical loan kit must already be included in the Australian Register of Therapeutic Goods (ARTG) (hence why the kit is exempt)
Oral products The Therapeutic Goods Administration (TGA) is responsible for regulating oral hygiene products such as toothpastes that are medicines or claims to have therapeutic use. Oral Hygiene products are 'therapeutic goods' if they: • Do not meet the relevant requirements of the Therapeutic Goods (Excluded Goods) Determination 2018, • Contain ingredients that are under the Poisons Standard, or • Make a therapeutic claim.		
Dental bleaches and whiteners	Excluded	As per Schedule 1, Item 3 of the Therapeutic Goods (Excluded Goods) Determination 2018.
Oral hygiene products such as dentifrices, mouth wash and breath fresheners for the care of the teeth and mouth where they: • do not contain any substance included in the Poisons Standard or • contain benefits/ claims only related to oral hygiene and/or prevention of tooth decay)	Excluded	As per Schedule 2, Item 6 of the Therapeutic Goods (Excluded Goods) Determination 2018.
• Salivation stimulation lozenge containing active ingredient	Medicine	Principal intended action of stimulating saliva production is primarily through pharmacological or metabolic means. These products usually contain an active ingredient that specifically stimulates salivation.
• Products used to cleanse dentures such as dental	Medical Device	These are accessories to a medical device (dentures) and are regulated as medical device. This is independent of their mode of action.

Product	Product category	Rationale
cleansing solutions and brushes for cleaning dentures		See Schedule 1 Item 5 of the Therapeutic Goods (Medical Devices - Specified Articles) Instrument 2020.
Other lozenges with therapeutic use		
• Anti-snoring dissolvable lozenge and other substances such as dissolvable oral strip, and throat spray/rinse that have active ingredient	Medicine	Products that have active ingredient and the therapeutic effect is achieved by pharmacological, immunological or chemical means are regulated as medicine. Products may have physical action such as lubrication but that will be an ancillary action.
• Throat lozenge to relieve sore throat and/or aid decongestion that have active ingredient	Medicine	Products that have active ingredient and the therapeutic effect is achieved by pharmacological, immunological or chemical means are regulated as medicine. Products may claim to have a physical action such as lubrication but that will be an ancillary action.
Incorporating both a medicine and a medical device		
Condom with spermicide or virucide	Medical Device	Principal intended action is primarily achieved through physical barrier, spermicide or virucide is ancillary action.
Catheter coated with heparin or antibiotic	Medical Device	Principal intended action is primarily achieved through physical means, heparin or antibiotic coating has an ancillary action.
Bone cement with antibiotic	Medical Device	Provides structural support and physical adhesion, the antibiotic has an ancillary action.
Active implantable medical device lead, steroid-eluting	Medical Device	Principal intended action is primarily achieved through physical means, steroid has an ancillary action.
Cardiac stent/lead, medicine-eluting	Medical Device	Principal intended action is primarily achieved through physical means, medicine has an ancillary action.
Intra ocular lens, heparin coated	Medical Device	Principal intended action is primarily achieved through physical means, heparin has an ancillary action.

Product	Product category	Rationale
Products such as tubing and catheters to carry blood, albumin coated	Medical Device	Principal intended action is primarily achieved through physical means, albumin has an ancillary action.
Copper intra uterine contraceptive device	Medical Device	Copper primarily works through physical action resulting in contraception.
Hormone-eluting intra uterine contraceptive device	Medicine	Hormone delivered by the intra uterine device results in contraception by pharmacological/metabolic means. The intra uterine device acts as a delivery mechanism.
Dental cement with antibiotic/adrenalin	Medical Device	Principal intended action is to provide structural support and bind to the teeth, which is through physical means. Antibiotic and adrenalin have ancillary action.
Dressings impregnated with medicinal product whose primary purpose is as a wound protectant	Medical Device	Principal intended action of the dressing is to protect the wound by physical means, the pharmacological action of the impregnated medicine is ancillary action.
Warming plasters (adhesive) containing capsaicin (capsicum oleoresin or capsicum extract) or mustard packs	Medicine	"Warming" sensation is achieved by pharmacological or metabolic means and are regulated as medicine.
Inhaler device – with medicine, non-refillable	Medicine	Products that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose). As per Schedule 1, item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.
Vapes containing a medicine (nicotine or cannabis), non-refillable	Medicine	
Inhaler device – refillable, supplied separately to medicine	Medical Device	Product is used for delivering the medicine and is not intended to form a single integral unit with the medicine. The medicine is typically sold separately. See • guidance on vapes and • guidance on reclassification of medical devices that administer
Vapes – refillable, supplied separately to medicine	Medical Device	

Product	Product category	Rationale
		medicines or biologicals by inhalation
Contact lenses – medicated for hypersensitivity	Medical Device	The medicine for hypersensitivity is ancillary to the contact lenses, which achieve the principal intended purpose by affecting light refraction.
Pre-filled or pre-loaded devices intended to deliver a medicine		
Syringes prefilled with a medicinal product (other than prefilled with sterile water/saline for catheter inflation)	Medicine	Articles that are intended to administer a medicine in such a way that the medicine and the article form a single integral product which is intended exclusively for use in the given combination and that are not reusable (may be multi-dose) are declared not to be medical devices as per Schedule 1, Item 3 of the Therapeutic Goods (Articles that are Not Medical Devices) Declaration 2023.
Transdermal patch	Medicine	
Intravenous nutrition etc. bags (filled)	Medicine	
Parenteral nutrition bags (filled)	Medicine	
Peritoneal dialysis bags (filled)	Medicine	
Oxygen and medical gas containers (filled) or delivery units	Medicine	
Internal sponge, membrane or similar for delivery of spermicide or Sexually transmitted disease (STD) virucide	Medicine	
Styptics (pencils, wool etc.)	Medicine	
Analgesic plasters	Medicine	
Medicated paste bandages	Medicine	
Corn/callus removal pads with medication	Medicine	
Unfilled or unloaded devices intended to deliver a medicine		
Blood bags (that contain and deliver an anticoagulant/preservative)	Medical Device	Products used for delivering medicine and is not intended to form a single integral unit with the medicine are medical devices. The medicine is typically sold separately.
Blood bags without anticoagulant/preservative	Medical Device	
Preservative solutions for use in blood bags	Medical Device	
Intravenous nutritional etc. bags (unfilled)	Medical Device	
Parenteral nutrition bags (unfilled)	Medical Device	
Peritoneal dialysis bags (unfilled)	Medical Device	

Product	Product category	Rationale
Oxygen and medical gas containers (unfilled)	Medical Device	
Tissue replacements of biological origin		
'Manufactured' from human tissue	Biological	As per section 32A (1)(a)(i) of the Act.
'Manufactured' from animal tissue and rendered non-viable	Medical Device	Product is a medical device as it incorporates non-viable tissue.
Products that comprise or contain live animal cells, tissues or organs	Biological	As per Schedule 1, Item 1 of the Therapeutic Goods (Biologicals - Specified Things) Instrument 2021.
Direct transplants	Excluded	As per Schedule 2, Item 4C of the Therapeutic Goods (Excluded Goods) Determination 2018.
Blood products	Medicine	Blood and blood components including haematopoietic progenitor cells and plasma derivatives are regulated as medicines. See blood and blood components
Tissue storage and transport solutions		
In-vitro fertilisation media	Medical Device	The primary intended action of storage is achieved through physical means and are regulated as medical devices. Actions achieved by active ingredient such as nutrients, antibiotics and anticoagulants will be ancillary. Products such as ex-vivo cell culture media or in-house solutions used in manufacturing of commercialised cell therapy products **are not** regulated as medical devices. See Australian regulatory guidelines for biologicals.
Other storage and transport solutions containing ingredients of animal origin	Medical Device	
Other storage and transport solutions containing ingredients of non-animal origin	Medical Device	
Topical compounds and products with therapeutic use		
Compound or solution for removal of warts by burning or freezing	Medical Device	Extreme temperature (hot or cold) resulting from heat transfer causing cell death is a physical means of action.

Product	Product category	Rationale
Topical nail treatment solutions containing antibacterial or antifungal ingredients	Medicine	Principal intended action is primarily achieved through pharmacological means by antibacterial or antifungal ingredient. May also contain ingredient that creates a physical barrier to exclude the micro-organism which will be considered as ancillary action.
Topical nail treatment solutions without antibacterial or antifungal ingredients	Medical Device	Products intended to treat infected nails by creating a physical barrier to protect from micro-organisms are regulated as medical devices.
Vascular access products		
Vascular access device locking solution that incorporate active ingredient such as an anticoagulant or antibiotic	Medical Device	Locking solutions use physical means (take up space) to maintain patency between infusions, prevent blood coagulating within the vascular access device, and prevent blood reflux. Active ingredients are considered ancillary.
Weight loss treatment - ingested		
Ingested weight loss treatments that occupy space in the stomach and are not absorbed	Medical Device	Weight loss treatments such as capsules that expand in the stomach act by physical means as they create a feeling of satiety by occupying space.
Ingested weight loss treatments that affect absorption of food	Medicine	If it affects absorption of calories in the gastrointestinal system by metabolic means.
Other products that have therapeutic use		
Ocular endotamponades such as gases and silicone oils	Medical Device	Products introduced into vitreous cavity for creating a physical tamponade are regulated as medical device.
Sodium alginate-based products for reflux	Medicine	They have a metabolic effect, altering the chemistry of gastric contents.
Therapeutic Sunscreens	Medicine	Non-exempt sunscreens are required to be listed under section 26A of the Act or registered under section 25 of the Act. See Australian regulatory guidelines for sunscreens.

Product	Product category	Rationale
Lithotripter	Medical Device	Principal intended action of breaking kidney stones to aid removal is achieved by physical means using high energy shoch waves.
Dissolution agent used with lithotripter	Medicine	Principal intended action of dissolving kidney stones to aid removal is achieved by pharmacological or metabolic means such as alkalisation of the urine.
Gums (as adhesives or lubricants) including Polyhydroxy compounds and Cellulose derivatives	Medical Device	Adhesives and lubricants primarily act by physical means and are regulated as medical devices.
Dusting powders, therapeutic uses	Medicine	Principal intended action is primarily achieved through pharmacological or metabolic means. Absorption of fluids by physical means is ancillary action.
Dextranomer dressing	Medical Device	Act by physical means to absorb wound exudate, wound debris, and micro-organisms.
Riboflavin eye drops intended for the treatment of keratoconus activated via illumination with Ultraviolet A (UVA) light	Medicine	UVA photoactivation of riboflavin eye drops increases collagen cross-linking in the cornea to strengthen the cornea which is achieved by pharmacological or metabolic means.
Urea, salicylic acid and other chemical preparations used to remove corn/callus	Medicine	Principal intended action is primarily achieved by metabolic means.
Substance that changes or buffers Potential of hydrogen (pH) in a lumen or cavity of the body	Medicine	Principal intended action is primarily achieved by metabolic means.
Radioactive sources and implants	Medical Device	Use energy to operate which is considered as physical means.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration	June 2004
V2.0	Updated publication	Medical Device Reforms Taskforce	April 2024

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
Web: tga.gov.au

Reference/Publication #