



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Boundary and combination products - medicines, medical devices, and biologicals

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TGA Health Safety
Regulation

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About this guidance

Under the *Therapeutic Goods Act 1989* (the Act), therapeutic goods are regulated as medicines, biologicals, medical devices or other therapeutic goods. However, in some cases, determining which therapeutic goods definition applies to a product and the appropriate regulatory pathway can be complex. There are some products that may appear to fall within more than one definition and require further analysis to determine which therapeutic goods definition applies, these are often referred to as 'boundary products'. This guidance sets out, in broad terms, principles to assist in determining which requirements within the Australian regulatory framework may apply to a certain product and lists some examples of these boundary products.

Within medical devices there are also other borderlines (for example with cosmetics, personal protective equipment, biocides etc). However, this document relates specifically to the differentiation between medical devices, medicines and biologicals.

These guidelines are to assist sponsors and manufacturers in determining the status of therapeutic goods that may not fit clearly within existing definitions for medicines, biologicals, or medical devices. In developing the list, the status of each product in the US and the European Union was considered with the desire that distinctions recognised in those jurisdictions be adopted where consistent with the Act.

The list of products (Appendix 1) includes guidance on the regulatory framework likely to apply to such products. In the case of products containing both medicine and device components, the TGA will evaluate both components even if the product overall is regulated as a medical device or medicine.

This guidance will assist in determining the most appropriate regulatory pathway for a product.. If in doubt sponsors should consult the TGA regarding the status of their product.

This information is provided for guidance only and should not be relied on to address every aspect of the relevant legislation.

The [therapeutic goods legislation](#) details the legal requirements for supplying therapeutic goods, including 'unapproved' goods, in Australia.

You should seek your own independent legal advice to ensure that all legislative requirements are met.

If you have feedback or require more information, you can email the following TGA areas

- [Prescription Medicines](#)
- [Over-the-counter medicines](#)
- [Medical Devices](#)
- [Biologicals](#)
- [TGA info](#)



Definitions

Medicine

Medicines are defined in Section 3 of the Act as therapeutic goods that are represented to achieve or are likely to achieve their principal intended action by pharmacological, chemical, immunological, or metabolic means in or on the body of a human.

Medical device

Medical devices are defined in section 41BD of the Act.

Notably, therapeutic goods that achieve their principal intended action in or on the human body by pharmacological, immunological, or metabolic means, are excluded from the definition of medical device. However, medical devices may be assisted in their function by such means.

Under subsections 41BD(2A) and (2B) of the Act, the Secretary may specify a particular instrument, apparatus, appliance, software, implant, reagent, material or other article, or particular class of such goods, as a medical device.

Similarly, under s 41BD(3) of the Act, the Secretary has the power to declare that a particular instrument, apparatus, appliance, software, implant, reagent, material or other article, or a particular class of such goods, as not being a medical device. Currently, under this provision, the delegate of the Secretary has declared a number of therapeutic goods not to be medical devices under the [Therapeutic Goods \(Articles that are not Medical Devices\) Order No. 1 of 2010](#).

[In appropriate cases, the Secretary may use these provisions to clarify the status of particular therapeutic goods or a class of therapeutic goods.](#)

Biological

Biologicals are defined in Section 32A of the Act, and are therapeutic goods comprising, containing, or are derived from human cells or human tissues and certain other products comprising or containing live animal cells, tissues, or organs.

Differentiating terms

In determining whether a product is expressly excluded for the definition of a medical device it is necessary to consider whether the principal intended action of a therapeutic good is by pharmacological, immunological or chemical means.

The principal intended action refers to the main mechanism of how it exerts its therapeutic effect and allows discrimination between types of therapeutic goods. It must be scientifically plausible considering the clinical indications the product is intended for use in and how physiological and/or pathological processes are affected; the principal intended action must be a desirable therapeutic effect that is verifiable.

Key therapeutic actions that discriminate between types of therapeutic goods are:

'Pharmacological means'¹ is understood as an interaction typically at a molecular level between a substance or its metabolites and a constituent of the human body which results in initiation, enhancement, reduction or blockade of physiological functions or pathological processes. Examples of constituents of the human body may include, among others: cells and their constituents (cell membranes, intracellular structures, RNA, DNA, proteins, e.g., membrane proteins, enzymes), components of extracellular matrix, foreign objects and organisms that are within the body, components of blood and components of body fluids.

Examples of action via pharmacological means:

- interaction between a ligand (e.g., agonist, antagonist) and a receptor
- interaction between a substance and membrane lipids
- interaction between a substance and components of the cytoskeleton
- interaction between a substance and a pathogenic organism

'Immunological means'² is understood as an action initiated by a substance or its metabolites on the human body and mediated or exerted (i.e., stimulation, modulation, blocking, replacement) by cells or molecules involved in the functioning of the immune system (e.g., lymphocytes, toll-like receptors, complement factors, cytokines, antibodies).

Examples of action via 'immunological means':

- modulation of an immune response (e.g., suppressing, blocking, activating, enhancing);
- replacement, reconstitution or introduction of natural or modified immune cells or molecules.
- triggering an immune response against the targeted tissues, cells or antigens by immune-specific recognition.
- targeting action of other linked or coupled substances.

Examples of substances acting via immunological means: vaccine, tetanus anti-serum, monoclonal antibodies, CAR-T cells, anti-venom, C1 esterase inhibitor.

When immunological recognition is used to target or direct the effects of linked or coupled substances, this recognition cannot be considered an ancillary³ action. Such products would therefore be deemed to act via immunological means and cannot be considered a medical device.

'Metabolic means'⁴ is understood as an action of a substance or its metabolites which involves an alteration, including stopping, starting or changing the rate, extent or nature of a biochemical process, whether physiological or pathological, participating in, and available for, function of the human body.

The term 'biochemical processes' is understood as reactions in the human body including anabolic and catabolic reactions and transport of substances between compartments. An interaction with a known receptor is not a prerequisite for the metabolic means of action.

Examples of action via 'metabolic means':

- the movement of water due to active transport of electrolytes mediated by e.g., Na/K ATPase pumps.

¹ Based on EU borderline guidance. MDCG 2022-5 - https://ec.europa.eu/health/system/files/2022-04/mdcg_2022-5_en_0.pdf

² Based on EU borderline guidance. MDCG 2022-5 - https://ec.europa.eu/health/system/files/2022-04/mdcg_2022-5_en_0.pdf

³ Ancillary – an accessory, subsidiary or helping thing – Macquarie Dictionary

⁴ Based on EU borderline guidance. MDCG 2022-5 - https://ec.europa.eu/health/system/files/2022-04/mdcg_2022-5_en_0.pdf

- inhibition of endogenous enzymes, including the digestive enzymes.
- inhibition of absorption of any substance in the alimentary or respiratory tracts.
- altering the electrolyte balance, including pH and osmolality, of the serum or other body compartment or cavity.

Registrable, listable or included goods

The Act, the Therapeutic Goods Regulations 1990 (the Regulations) and the Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations) provide that the ARTG has 5 parts, one relating to registered goods, one relating to provisionally registered goods, one relating to listed goods, one relating to biologicals and the other relating to medical devices.

Registrable and listable goods are regulated under Chapter 3 of the Act. Registrable goods undergo a more rigorous evaluation of their quality, safety and efficacy, before being entered into the ARTG, than listable goods.

Medical devices are regulated under Chapter 4 of the Act and can be included in the ARTG if they comply with the Essential Principles for safety and performance, have undergone appropriate conformity assessment procedures (or comparable overseas regulator pathways), and certain other requirements are complied with.

Exemptions from the inclusion provisions of medicines and biologicals are published in Schedules 5 and 5A of the Regulations (exempt goods) and exemptions from inclusion of medical devices in Schedule 4 of the MD Regulations.

Biologicals are included in the ARTG and are classified into one of four regulatory classes.

The Secretary may declare specific therapeutic goods to either be or not be a biological. Goods declared to not be a biological are regulated by the TGA as either a medicine or a medical device but are not included in the Biologicals Regulatory Framework at this time. These products are included in the Therapeutic Goods (Things that are not Biologicals) Determination No.1 of 2011, available at <https://www.legislation.gov.au/Details/F2011L00894>

Other therapeutic goods

Other therapeutic goods do not fit the definition of a medical device nor a medicine but are regulated as listed therapeutic goods or exempt from entry on the ARTG, under Chapter 3 of the Act. This includes sterilants, disinfectants, tampons, and menstrual cups.

Sterilants and disinfectants are regulated in a variety of ways in Australia, depending on the intended purpose of the product as discerned from the claims made in the instructions for use, labelling and promotional material. Specific information and guidance on these products are available on the TGA website - [Disinfectants, sterilants and sanitary products](#).

Boundary products

Boundary products are therapeutic goods that may have some of the attributes of two or more categories of regulated goods, or they may simply be products for which the appropriate regulatory pathway is not immediately obvious.

The action of a medicinal product is typically achieved by pharmacological, chemical, immunological or metabolic means. Note that a substance administered for diagnostic purposes, (i.e. an in vivo diagnostic substance), even though it does not act in such ways, is also usually considered to be a medicinal product.

In the case of a medical device, the principal intended action is typically fulfilled by physical means (including mechanical action, solid physical barrier protecting the surface it is applied to, replacement of, or support to, organs or body functions).

Any therapeutic goods that are chemical substances and exert their therapeutic effect through local or systemic chemical means are generally **not** medical devices. The pharmacological properties of such products are critical to the evaluation of their safety and efficacy.

In deciding how these products are regulated, the TGA considers:

- which component or ingredient of the product provides the most important therapeutic effect of the product
- the principal therapeutic effect achieved, when used consistently with the sponsor/manufacturer's claims i.e. intended use
- the primary mode of action of the product in achieving its therapeutic effect and how it relates to the definitions of medicine, biological and medical device.

Determination of the principal therapeutic effect may be influenced by factors such as:

- actual therapeutic effect of the product and scientifically demonstrated action, verifiable in humans through clinical study findings
- therapeutic claims made for the product, including any made on websites, linked helplines, testimonials and publications; product names and branding may be deemed implicit claims
- the context in which the claims are made, and the overall presentation
- the labelling, packaging/package inserts, pamphlets and promotional literature, including any pictures or graphics
- advertisements, including those appearing in "advertorials", on television, other media and the Internet
- the product form (capsule, tablet, injection etc.) and the way it is to be used.



The addition of one substance may be enough to change the principal therapeutic effect of the product and hence the type of therapeutic good that the product falls under.

Medical devices may contain medicinal substances, including herbal and plant extracts and substances derived from human blood or blood plasma, that act on the body in a manner ancillary to the device. However, when such substances act in a manner that is more than ancillary, the product is likely to be regulated as a medicine.

For these boundary products containing a medicine component and a medical device component a product deemed to be a:

- medicine will be assessed through the medicine pathways, with input from the devices evaluation area
- medical device will be assessed through the device pathways, with input from the medicines evaluation area.

Note that System or Procedure Packs have specific guidance available at [System or procedure packs | Therapeutic Goods Administration \(TGA\)](#).

The decision on approval will be issued by the lead program.

For more information on the regulatory requirements:

Therapeutic good	Regulatory requirements
medical devices	Medical devices & IVDs
other therapeutic goods	Other therapeutic goods
prescription medicines	Australian Regulatory Guidelines for Prescription Medicines
OTC medicines	Australian Regulatory Guidelines for OTC Medicines
complementary medicines	Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines
Biologicals	Australian Regulatory Guidelines for Biologicals

Combination products

Medicine-device combinations

Medical devices that incorporate, or are used to administer, a medicine are regulated as either medical devices or as medicinal products, depending on the primary intended purpose of the product.

Three types of medicine-device combinations

There are three main types of medical devices that incorporate, or are used to administer, a medicinal product:

Devices that are used to administer a medicine

For example, a syringe marketed empty, medicine spoons, droppers etc. These products are normally regulated as medical devices when supplied separately.

When medicine measures are co-packaged with or contained within the same pack as the medicine and where the device is intended to be used to measure or administer the medicine in the pack, the entire product is regulated as a medicine. Example is paracetamol oral liquid and its measuring syringe or a cup. The device component does not have to be included in the ARTG.

Devices for administering medicines where the device and the medicine form a single integral product designed to be used exclusively in the given combination and that are not re-usable or refillable

Note that this circumstance is covered by the [Therapeutic Goods \(Articles that are not Medical Devices\) Order No. 1 of 2010](#)

For example, a syringe marketed pre-filled with a medicine, or an asthma puffer. These products are regulated as medicines, although in addition to this, the relevant Essential Principles of Schedule 1 of the MD Regulations apply with respect to safety and performance related features of the device (e.g. a syringe forming part of such a product). The device component does not have to be included in the ARTG.

Devices incorporating, as an integral part, a substance, that, if used separately, may be considered to be a medicine and where the substance is liable to act upon the body with action ancillary to that of the device.

For example, a heparin coated catheter. These products are regulated as medical devices. In addition, the safety, quality and usefulness of the medicinal substance must be verified by the relevant Branch of the TGA. Note that 'medicine' in this context includes all substances that may be considered to be medicines, including herbal medicines (including herbal and plant extracts) and substances derived from human blood or blood plasma.

'Integral' is usually taken to mean a single component product. However, there may be circumstances where it may be taken to mean two elements that are packaged together and combined into one product immediately prior to administration to the patient.

Note that medicine device combinations may be covered by System or Procedure Packs and there is specific guidance on these available at [System or procedure packs | Therapeutic Goods Administration \(TGA\)](#).

Biological – medical device combinations

Biologicals presented as a combination product with a medical device component (i.e. integrated with the medical device), such as a metal stent coated with a matrix and endothelial cells, are regulated under the Biologicals Regulatory Framework and included in the ARTG as a biological. The device (e.g. the metal stent itself) will be assessed according to medical device regulatory requirements but will not be included in the ARTG separately.

Biological – medicine combinations

Biologicals presented as a combination product with a medicine component are regulated under the Biologicals Regulatory Framework and included in the ARTG as a biological e.g. CAR-T with ligand/Ab.

Excluded goods

The Secretary may, by publication of an Order declare that particular goods are not, for the purposes of the Act, therapeutic goods. Information on Excluded Goods is available on the TGA website at [Excluded goods orders, determinations and specifications](#).

Exempt goods

After determining the appropriate regulatory framework for a therapeutic product, it would be necessary to see if any exemptions apply to the goods. It should be noted that even if the good is exempt this may only be from entry on the ARTG, and other aspects of the regulatory framework continue to apply.

Specific Boundary Product Guidance

Refer to [Appendix 1](#) of this guidance for more information on specific boundary products and which regulatory pathway is applicable.

Appendix 1

Guidance on product regulatory pathway

Product	Regulatory Pathway
Absorbable, with shape, used in surgery:	
• sutures	Medical Device
• staples	Medical Device
• bone fixation devices	Medical Device
• resorbable bone plates (polylactic/polyglycolic acid)	Medical Device
• sponges (not for use as an antiseptic)	Medical Device
• tissue adhesives (may include fibrin-based adhesives)	Medical Device
Absorbable, without shape, used in surgery:	
• visco-elastic fluids	
– intra-ocular	Medical Device
– synovial (<i>animal origin</i>)	Medical Device
• haemostatic agents (collagen)	Medical Device e.g. vessel sealant or matrix
• haemostatic agents (fibrin)	Medicine e.g. activation of clotting mechanism
Absorbable 'long-term':	
• collagen injections	Medical Device
• hyaluronic acid injections	Medical Device when used as filler or lubricant
Hard-tissue scaffolds	
• hydroxyapatite (with or without collagen)	Medical Device
• calcium phosphate (with or without collagen)	Medical Device
• coral	Medical Device
• bioglass	Medical Device
• cartilage repair systems	Medical Device/Biological
Body 'cleaning' substances:	
• bulk laxatives	Medicine
• salt solution laxatives	Medicine
• gastrointestinal detoxifier	Medicine
• enema solutions	Medicine
• medicated mouthwashes	Medicine
• douches	Medical Device
• solutions for irrigation (e.g., Pre-Filled Saline Syringe - Catheter, flush syringe, eye irrigation solution)	Medical Device
• activated charcoal used internally	Medicine

Product	Regulatory Pathway
<ul style="list-style-type: none"> isotonic saline for nasal irrigation 	Medical Device
<ul style="list-style-type: none"> Hypertonic saline for inhalation 	Medicine
<ul style="list-style-type: none"> Hypertonic eye drop 	Medicine
Body fluid replacements and nutrients:	
<ul style="list-style-type: none"> electrolyte solutions 	Medicine
<ul style="list-style-type: none"> plasma expanders 	Medicine
<ul style="list-style-type: none"> total parenteral nutrition solutions 	Medicine
<ul style="list-style-type: none"> blood substitutes 	Medicine
<ul style="list-style-type: none"> peritoneal dialysis solutions & substances prepacked for their preparation 	Medicine
<ul style="list-style-type: none"> haemofiltration solutions 	Medicine
<ul style="list-style-type: none"> haemodialysis solutions not in direct contact with blood i.e. other side of membrane 	Medical Device
<ul style="list-style-type: none"> artificial tears for use with/without contact lenses (unmedicated) 	Medical Device
<ul style="list-style-type: none"> artificial saliva 	Medical Device
Medical gases	
<ul style="list-style-type: none"> oxygen & other medical gases (except cryogenic gases and gases for mechanical use) 	Medicine
<ul style="list-style-type: none"> oxygen – chemical generators 	Medicine
<ul style="list-style-type: none"> Gas used as a diagnostic 	Medicine
<ul style="list-style-type: none"> oxygen concentrators 	Medical Device
<ul style="list-style-type: none"> ozone generators 	Medical Device
<ul style="list-style-type: none"> cryogenic gases 	Medical Device
<ul style="list-style-type: none"> gases for mechanical use 	Medical Device
Diagnostic imaging or similar agents (<i>in vivo</i>)	
Diagnostic imaging or similar agents (<i>in vivo</i>) for use in conjunction with:	
<ul style="list-style-type: none"> positron emission tomography 	Medicine
<ul style="list-style-type: none"> computerised axial tomography 	Medicine
<ul style="list-style-type: none"> nuclear magnetic resonance 	Medicine
<ul style="list-style-type: none"> ultrasonography 	Medicine
<ul style="list-style-type: none"> X-Ray 	Medicine
<ul style="list-style-type: none"> gas mixtures for pulmonary function testing devices 	Medicine
<ul style="list-style-type: none"> radionucleotide scanning 	Medicine
Agents injected, ingested, instilled or applied	
Agents injected, ingested, or otherwise instilled into or applied to the body for use in device therapy:	
<ul style="list-style-type: none"> laser fluorescent dyes 	Medicine
<ul style="list-style-type: none"> fluorescein ocular drops/strips 	Medicine

Product	Regulatory Pathway
• injectable fluorescein	Medicine
• ocular endotamponades	Medical Device
• laser/UV light activated agents	Medicine
• lithotripsy imaging agents	Medicine
• radioactive sources and implants	Medical Device
• electrode gels	Medical Device
• lubricants	Medical Device
• lubricants with spermicide/virucide	Medical Device
• refrigerant sprays	Medical Device
• cryogenic and refrigerant gases	Medical Device
• gases for mechanical use only	Medical Device
• Ingested Weight loss treatments that occupy space in the stomach	Medical Device
• Sodium alginate based products for reflux	Medicine
Diluents and preservatives for medicines	
• water for injections	Medicine
• saline for injections	Medicine
• blood anti-coagulants and preservatives (for subsequent in vivo use)	Medicine
External use without added active substance	
• emollient & moisturising preparations, formulated & presented for therapeutic use	Medicine
• Uncompounded emollients, moisturisers presented for therapeutic use	Medical Device
• barrier product that provides a physical barrier effect e.g. stoma cream	Medical Device
• barrier product due to a chemical or pharmacological effect including selective exclusion of infective pathogens	Medicine
• any of above four with non-therapeutic presentation	Not Therapeutic Good
• non medicated skin cleansers and adhesives	Not Therapeutic Good
• non medicated soaps	Not Therapeutic Good
• adhesive removers	Not Therapeutic Good
• skin adhesive and adhesive enhancers	Medical Device
Products incorporating both a medicine and a medical device	
• condom with spermicide	Medical Device
• condom with virucide	Medical Device
• catheter with heparin coating	Medical Device
• catheter with antibiotic coating	Medical Device
• bone cement with antibiotic	Medical Device
• active implantable medical device lead, steroid-eluting	Medical Device

Product	Regulatory Pathway
• medicine-eluting cardiac stent / lead	Medical Device
• intra ocular lens heparin coated	Medical Device
• devices albumin coated	Medical Device
• copper intra uterine contraceptive device	Medical Device
• hormone-eluting intra uterine contraceptive device	Medicine
• dental cement with antibiotic/adrenalin	Medical Device
• dressings impregnated with medicinal product	Medical Device (unless primary purpose is to deliver the medicinal substance in which case it is a medicine)
• hydrogel wound dressings	Medical Device
• Medicine with non-refillable inhaler device	Medicine
• Refillable medical device e.g. inhaler, supplied separately to medicine	Medical Device
• Contact lenses with medicine for hypersensitivity (medicated)	Medical Device
Sunscreens	
• when meets the definition of therapeutic goods	Medicine
Tissue replacements of biological origin:	
• 'manufactured' from human tissue	Biological
• 'manufactured' from animal tissue and rendered non-viable	Medical Device
• products that comprise or contain live animal cells, tissues or organs	Biological
• direct transplants	Excluded
• blood products	Medicine
• blood & blood components	Medicine
• blood substitutes and expanders	Medicine
Pre-filled or pre-loaded devices intended to deliver a medicine:	
• syringe (other than prefilled with sterile water/saline for catheter inflation)	Medicine
• transdermal patch	Medicine
• hormone eluting IUD	Medicine
• IV nutrition etc. bags (filled)	Medicine
• parenteral nutrition bags (filled)	Medicine
• peritoneal dialysis bags (filled)	Medicine
• oxygen & medical gas containers (filled) or delivery units	Medicine
• oxygen & medical gas containers (empty)	Medical Device
• internal sponge, membrane or similar for delivery of spermicide or STD virucide	Medicine

Product	Regulatory Pathway
<ul style="list-style-type: none"> • styptics (pencils, wool etc.) 	Medicine
<ul style="list-style-type: none"> • corn, callus removal pads with medication 	Medicine
<ul style="list-style-type: none"> • analgesic plasters 	Medicine
<ul style="list-style-type: none"> • medicated paste bandages 	Medicine
<ul style="list-style-type: none"> • gingival retraction cords coated with adrenalin 	Medicine
<ul style="list-style-type: none"> • gingival retraction cords coated with astringent 	Medical Device
Unfilled or unloaded devices intended to deliver a medicine:	
<ul style="list-style-type: none"> • blood bags (that contain & deliver an anticoagulant/preservative) 	Medical Device
<ul style="list-style-type: none"> • blood bags without anticoagulant/preservative 	Medical Device
<ul style="list-style-type: none"> • preservative solutions for use in blood bags 	Medical Device
<ul style="list-style-type: none"> • IV nutritional etc. bags (unfilled) 	Medical Device
<ul style="list-style-type: none"> • parenteral nutrition bags (unfilled) 	Medical Device
<ul style="list-style-type: none"> • peritoneal dialysis bags (unfilled) 	Medical Device
<ul style="list-style-type: none"> • gas cylinders for medical gases (unfilled) 	Medical Device
System or procedure packs	
Information on system and procedure packs is available at System or procedure packs - Guidance for sponsors, manufacturers and charities	
Dual-treatment goods	
<ul style="list-style-type: none"> • lithotripter 	Medical Device
<ul style="list-style-type: none"> • dissolution agent used with lithotripter 	Medicine
Diagnostic goods for <i>in vitro</i> use	
<ul style="list-style-type: none"> • that incorporate material of human origin 	Medical Device
<ul style="list-style-type: none"> • for self diagnosis (home use) 	Medical Device
<ul style="list-style-type: none"> • in vitro test kits other than above 	Medical Device
Extra-corporeal therapies	
<ul style="list-style-type: none"> • immunoadsorption columns <ul style="list-style-type: none"> – charcoal activated – monoclonal antibodies 	Medical Device
<ul style="list-style-type: none"> • haemoperfusion columns 	Medical Device
Tissue storage and transport solutions	
<ul style="list-style-type: none"> • In vitro fertilisation media 	Medical Device
<ul style="list-style-type: none"> • other storage & transport solutions containing ingredients of animal origin 	Medical Device

Product	Regulatory Pathway
<ul style="list-style-type: none"> other storage & transport solutions containing ingredients of non-animal origin 	Medical Device
Apheresis Solutions	
<ul style="list-style-type: none"> Apheresis Solutions 	Medical Device
Diagnostic goods for <i>in vivo</i> use	
<ul style="list-style-type: none"> Allergen skin tests 	
<ul style="list-style-type: none"> – scratch test 	Medicine
<ul style="list-style-type: none"> – patch 	Medicine (Exempt)
<ul style="list-style-type: none"> labelled urea for H pylori test 	Medicine
<ul style="list-style-type: none"> tartaric acid for testing patient reflex cough 	Medicine
Contact lens care products	
<ul style="list-style-type: none"> contact lens cleaning, disinfecting, rinsing or hydrating solutions 	Medical Device
<ul style="list-style-type: none"> wetting agents 	Medical Device
<ul style="list-style-type: none"> hydrating agents 	Medical Device
<ul style="list-style-type: none"> comfort drops 	Medical Device
<ul style="list-style-type: none"> soft contact lens lubricants 	Medical Device
<ul style="list-style-type: none"> hard contact lens lubricants 	Medical Device
Oral Care Products	
<ul style="list-style-type: none"> toothpaste (SUSMP scheduled or with therapeutic claims beyond permitted oral hygiene claims) 	Medicine
<ul style="list-style-type: none"> toothpaste other 	Not Therapeutic Good
<ul style="list-style-type: none"> tooth whitener 	Excluded
<ul style="list-style-type: none"> Brush for cleaning dental implants 	Medical Device
<ul style="list-style-type: none"> Salivation stimulation lozenge 	Medicine/Not a therapeutic good if unmedicated
<ul style="list-style-type: none"> Throat lozenge 	Medicine/Not a therapeutic good if unmedicated
Antiseptics, disinfectants, cleaners, soaking solutions	
<ul style="list-style-type: none"> antiseptics for use on skin, 	Medicine
<ul style="list-style-type: none"> antiseptic 'wipe' or sponge 	Medicine
<ul style="list-style-type: none"> paper tissue with: 	
<ul style="list-style-type: none"> – antiseptic 	Medicine
<ul style="list-style-type: none"> – virucide 	Medicine
<ul style="list-style-type: none"> alcohol swab (with antiseptic claim) 	Medicine
<ul style="list-style-type: none"> alcohol swab (with no claims other than cleaning the skin) 	Medical Device
<ul style="list-style-type: none"> fabric dressing with antiseptic 	Medical Device (<i>unless primary purpose is to deliver the antiseptic</i>)

Product	Regulatory Pathway
• sterilants (except sterilant gases) for use on medical devices	Medical Device
• instrument grade disinfectant	Medical Device
• hospital grade disinfectant with specific claims*	Other Therapeutic Good (Listable)
• household/commercial grade with specific claims*	Other Therapeutic Good (Listable)
• hospital grade disinfectants with non-specific claims*	Other Therapeutic Good (Exempt)
• household/commercial grade disinfectants with non-specific claims*	Other Therapeutic Good (Exempt)
• ostomy appliance detergents, deodorisers	Not Therapeutic Good
• cleaners and sanitisers not making disinfectant claims	Not Therapeutic Good
Other	
• gums (as adhesives or lubricants)	Medical Device
• polyhydroxy compounds	Medical Device
• cellulose derivatives	Medical Device
• petroleum jelly	Medical Device
• dusting powders, non-therapeutic	Not Therapeutic Good
• dusting powders, therapeutic uses	Medicine
• ostomy dressings	Medical Device
• dextranomer dressing	Medical Device
• substances used to treat head lice/nits on the human body	Medicine
• Products that facilitate physical removal of head lice e.g. head lice comb, including those with an electro-action, and lubricants.	Medical Device
• warming plasters (adhesive) containing capsaicin (capsicum oleoresin or capsicum extract) or mustard packs	Medicine
• riboflavin eye drops intended for the treatment of keratoconus activated via illumination with UVA light	Medicine
• Dentistry products with aluminium chloride are used for haemostasis	Medical Device
• Urea, salicylic acid and other chemical preparations used to remove corn/callus	Medicine
• Substance that changes or buffers pH in a lumen or cavity of the body	Medicine
• Nail fungus treatment solution with no anti-bacterial or anti-fungal ingredients	Medical Device
• Nail fungus treatment solution with anti-bacterial or anti-fungal ingredients	Medicine

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Section/Office	October 2022

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Reference/Publication #