Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Classification of medical devices that are not IVDs

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About

This document aims to help manufacturers in correctly classifying their devices. It is part of the Steps to supply medical device guidance for manufacturers.

Read this along with MD Regulations

This document will help you understand medical device classification rules. It's not a substitute for reading the Regulations and Explanatory Statements.

This document **does not** include guidance on:

- Confirm your product is a medical device that needs to be included in the ARTG
- boundary and combination products
- Classification of IVD medical devices
- medical devices intended to be supplied sterile
- medical devices with a measuring function.

Introduction

Devices manufactured for Australian supply must have regulatory evidence.

Classification is one of the factors used to determine minimum acceptable regulatory evidence.

The responsibility for classifying your medical devices lies with you (not your sponsors). In part, this is because you know your devices better than anyone else.

Classification rules vary in different regulatory jurisdictions

If you are a manufacturer, you must consider the Australian legislation when determining the classification of a device that is to be supplied in Australia.

You are responsible for determining the classification of a device using a set of classification principles and rules according to your intended purpose for your device.

- Identical devices may be classified differently if they are intended to be used in different ways. For example, in different parts of the body, by relevant health professionals or not, or in conjunction with other devices.
- Your intended purpose for your device is important factor in determining the appropriate classification.

Classification tiers

There are two sets of classification rules.

One set applies to devices that are not in vitro diagnostic (IVD) medical devices.

The other set applies to IVD medical devices. Both non-IVDs and IVDs have four classification tiers.

From highest to lowest, these are:

- Class III / Class 4 IVD
- Class IIb / Class 3 IVD
- Class IIa / Class 2 IVD
- Class I / Class 1 IVD.

The higher the Class, the higher the level of regulatory requirements that apply.

Each tier maps to minimum combinations of acceptable regulatory evidence you must hold. You have a choice of which regulatory evidence to hold equal to or higher than the minimum.

The process

- The Therapeutic Goods (Medical Devices) Regulations 2002 (MD Regulations) include a set of principles for how to classify your device.
- The principles state that your device takes the highest resulting Class when more than one rule applies.

Schedule 2 details the classification rules for medical devices that are not IVDs.

Schedule 2A details the classification rules for IVD medical devices.

Regulation 3.3 details the principles for applying the classification rules.

Based on:

- your intended purpose for your device
- various properties your device might hold.

It's essential that you classify each model of device you manufacture on a case-by-case basis.

This is because no two models of device are the same.

Principles for applying the classification rules

The medical device classification principles are outlined in Regulation 3.3 of the MD Regulations.

In some cases, more than one rule can apply.

If this happens, the higher classification applies, except for medical devices for export only (Rule 5.8), which are classified as Class I.

You must be considered all the classification rules to determine the classification of your medical device.

Accessories are classified separately to the medical device they are intended to be used with.

If your device is to be used in combination with another medical device, the classification rules must be applied separately to each device.

For systems and for procedure packs, the classification for the entire system or pack is the highest classification of any individual device in the system or pack.

A system or procedure pack that contains both IVD and non-IVD medical devices that have the same level of classification under the table in regulation 3.1 is treated according to its primary intended purpose (as an IVD or non-IVD).

The presence of a medicine in a procedure pack does not affect the classification of the pack.

For example, if the device with the highest classification in the pack is Class IIa, then the entire pack is classified as Class IIa, irrespective of whether the pack contains a medicine or not.

If your medical device is intended to be used in more than one part of a patient's body, your device is classified according to the part of the body that results in the highest classification.

Personalised medical devices are classified in the same way as all other medical devices.

Introduction to the individual classification rules

You must consider all the classification rules below when classifying your medical device.

Classification principle 3.3(7) states that more than one classification rule can apply.

The correct classification is the highest applicable classification rule, except in the case of devices intended for export only, which are always **Class I** per Rule 5.8.

The classification rules are outlined in Schedule 2 of the MD Regulations.

When classifying your device, consider:

- classification principles (MD Regulation 3.3)
- classification rules (MD Regulations, Schedule 2)
- defined terms relating to classification in the MD Regulations Dictionary.

Rule 1: Transient, short-term, and long-term use

Rule 1 applies to all medical devices, as it determines intended duration of use. Intended duration of use is a classification factor in several other rules.

- **Transient** use is for a continuous period of **less than 60 minutes.**
- **Short-term** use is for a continuous period of **at least 60 minutes but not more than 30 days**.
- **Long-term** use is for a continuous period of **more than 30 days.**
- For the purposes of determining whether your device is intended to be used continuously, you should disregard temporary interruptions or removals, such as for cleaning, eating or sleeping.

Rule 2: Non-invasive and non-active

Rule 2 applies if none of the other rules listed below apply to your medical device.

Examples include non-invasive and non-active devices that are intended to:

- collect body liquid where a return flow is unlikely
- immobilise body parts

- apply force or compression
- channel or store substances that will eventually be delivered into the body
- treat or modify substances that will be delivered into the body
- dress wounds.

Classifications vary depending on the device's intended purpose.

Rule 3: Invasive

Rule 3 applies if the medical device is invasive – meaning it penetrates the body through a body orifice or is inserted into the body during surgery.

Examples include:

- anoscopes
- colonoscopes
- eye cannulas
- internal tympanostomy tubes
- intraoral X-ray sensors
- joint implants
- ophthalmic knives
- oral gags
- oral suction units
- proctoscopes
- sets of ear, nose or throat forceps
- stomal pegs
- surgical eye probes
- surgical meshes
- thermometers
- tongue depressors
- tracheostomy tubes
- urethral bougies
- vaginal specula.

Classifications vary depending on the device's intended purpose.

Rule 4: Active

Rule 4 applies if the medical device is active – meaning it depends on a source of energy for its operation and converts that energy in a significant way.

Rule 4 also applies to devices that incorporate or are software-based medical devices.

Examples include:

- diagnostic X-ray sources
- magnetic resonance imaging
- mobile phone/tablet apps
- websites
- air-driven surgical drills and saws
- patient monitors
- electronic blood pressure measuring devices
- diagnostic ultrasound
- electronic stethoscopes or thermometers
- powered (e.g., electrical or chemical) hot or cold packs
- software
- gas regulators
- radioactive seeds
- mechanical infusion systems.

Classifications vary depending on the device's intended purpose.

Rule 5: Rules for particular kinds of devices

There are multiple sub-rules that apply to specific kinds of devices as described in Schedule 2, Part 5 of the Regulations.

Each sub-rule has its own decision tree showing how to apply them when classifying your medical device.

Rule 5.1: Contain a medicine

Rule 5.1 applies if the medical device **contains a medicine**.

Examples include:

- antibiotic bone cements
- condoms with spermicide
- heparin-coated catheters
- dressings incorporating an antimicrobial agent.

These devices are all **Class III**. Classifications vary depending on the device's intended purpose.

See Boundary and combination products.

Rule 5.2: Contraception or STD prevention

Rule 5.2 applies if the medical device is for **contraception or preventing sexually transmitted diseases**.

Examples include:

- condoms
- contraceptive diaphragms
- contraceptive intrauterine devices (IUDs) that are not hormone-eluting
- surgically implanted contraceptive devices.
- Classifications vary depending on the device's intended purpose.

Rule 5.3: Disinfecting, cleaning, rinsing, or hydrating

Rule 5.3 applies if the medical device is for disinfecting, cleaning, rinsing, or hydrating.

Examples include:

- contact lens solutions
- comfort solutions
- disinfectants for haemodialysis devices and endoscopes
- sterilisers to sterilise medical devices
- washer disinfectors.

Classifications vary depending on the device's intended purpose.

Rule 5.4: Used in patient imaging and anatomical models

Rule 5.4 applies if the medical device is used to **record patient images**, is **used to generate a virtual anatomical model**, or **is itself an anatomical model**.

Examples include:

- X-ray detectors
- X-ray film
- stereotaxic devices used to capture images to support treatment planning (including printing anatomical models for the purpose of surgical planning)
- software intended to record images of soft-tissue injury captured from an ultrasound imaging device
- a 3D-model of the myocardium for identifying ventricular septal defects
- software that is intended to generate a 3D anatomical virtual model from patient scans for the purpose of a health professional diagnosing a stress fracture.

These devices are all **Class IIa**.

Rule 5.4 vs other diagnosing and monitoring rules

Many of the devices captured by Rule 5.4 will also be captured by Rules 4.3, 4.5, and 4.6. When more than one rule applies, the device is classified according to the higher resulting Class.

Classifications vary depending on the device's intended purpose.

Rule 5.5: Containing non-viable animal tissues or their derivatives

Rule 5.5 applies if your device **contains non-viable animal tissues or their derivatives**.

Examples include:

- biological heart valves
- porcine xenograft dressings
- catgut sutures
- implants and dressings made from collagen
- intra-ocular fluids
- meniscal joint fluid replacement
- anti-adhesion barriers
- tissue fillers based on hyaluronic acid derived from bacterial fermentation processes.

These devices are all **Class III**.

Rule 5.6: Blood bags

Rule 5.6 applies if the medical device is **a blood bag (including those containing or coated with an anticoagulant)**.

These devices are all **Class IIb**. Classifications vary depending on the device's intended purpose.

Rule 5.7: Active implantable

Rule 5.7 applies if the medical device is **an active implantable medical device**.

Examples include:

- implantable pacemakers
- defibrillators
- nerve stimulators.

These devices are all **Class III**.

Rule 5.7 also applies for **an implantable accessory to an active implantable medical device**.

Examples include:

- cochlear implant system coil
- defibrillation lead electrical extension adaptor
- cochlear implant magnets

These devices are all **Class III.**

Rule 5.7 also applies if the medical device is **an active medical device intended to control, monitor, or directly influence the performance of an active implantable medical device**.

Examples include:

- clinician's programming devices for pacemakers
- patient control devices for nerve stimulation devices.

These devices are all **Class III.** Classifications vary depending on the device's intended purpose.

Rule 5.8: For export only

Rule 5.8 applies if the medical device is intended for **export only**.

These devices are all **Class I**. This is a special rule. Devices intended for export only are *always* Class I.

Rule 5.9: Mammary (breast) implants

Rule 5.9 applies if the medical device is a **mammary (breast) implant**.

These devices are all **Class III**.

Rule 5.10: Administered by inhalation

Rule 5.10 applies if your device is intended to be used for the **administration of medicine or biologicals by inhalation**.

Examples include:

- laryngeal mask airway
- nebuliser
- endotracheal tube

Classifications vary depending on your device's intended use.

Rule 5.11: Substances introduced into the body or absorbed by the skin

Rule 5.11 applies if the device **is composed of a substance, or a combination of substances,** that are to be **introduced into the body through an orifice or applied to and absorbed by the skin**.

Examples include:

- saline nasal spray
- eye lubricant

Classifications vary depending on your device's intended use.

Classification rules in more detail

Rule 1: Transient, short-term, and long-term use

You must take into consideration the intended duration of continuous use when determining the classification of your medical device.

- **Transient** use is for a continuous period of **less than 60 minutes**.
- **Short-term** use is for a continuous period of **at least 60 minutes but not more than 30 days**.
- **Long-term** use is for a continuous period of **more than 30 days**.

For the purposes of determining whether your device is intended to be used continuously, you should disregard temporary interruptions or removals, such as for cleaning, eating or sleeping.

Rule 2: Non-invasive

There are four sub-rules related to non-invasive medical devices, described in Schedule 2, Part 2 of the Regulations.

Each sub-rule has its own decision tree showing how to apply them when classifying your device.

Sub-rule 2.1: Non-invasive

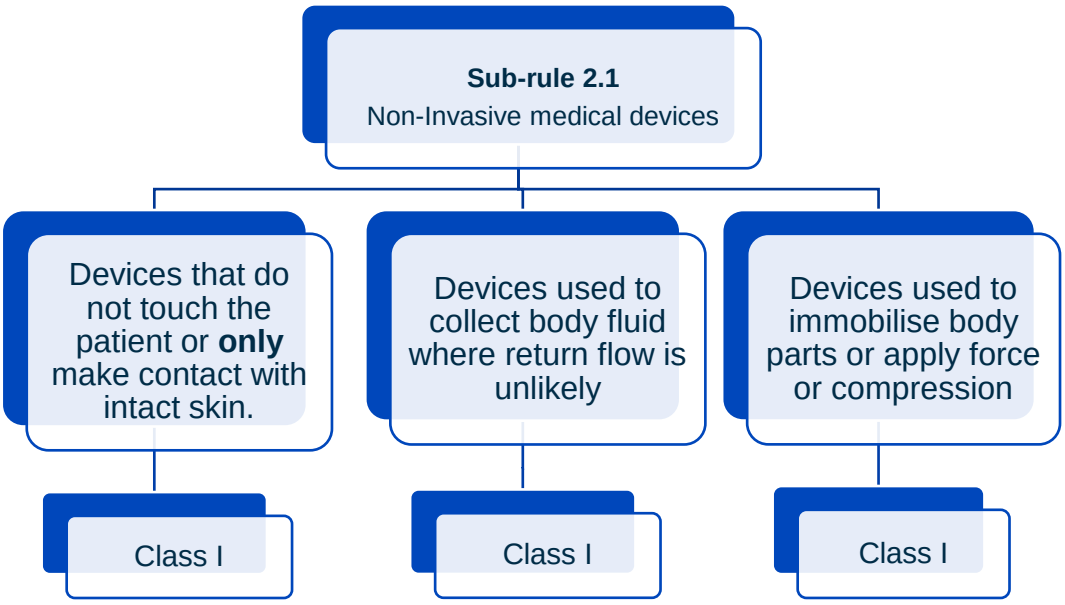
Sub-rule 2.1 states that unless it is classified at a higher level under another rule in Schedule 2 of the Regulations, **a non-invasive medical device is Class I**.

This rule applies to:

- devices that **only** have contact with intact skin
- devices that do not touch the patient.

These include devices used to collect body liquid where a return flow is unlikely, such as:

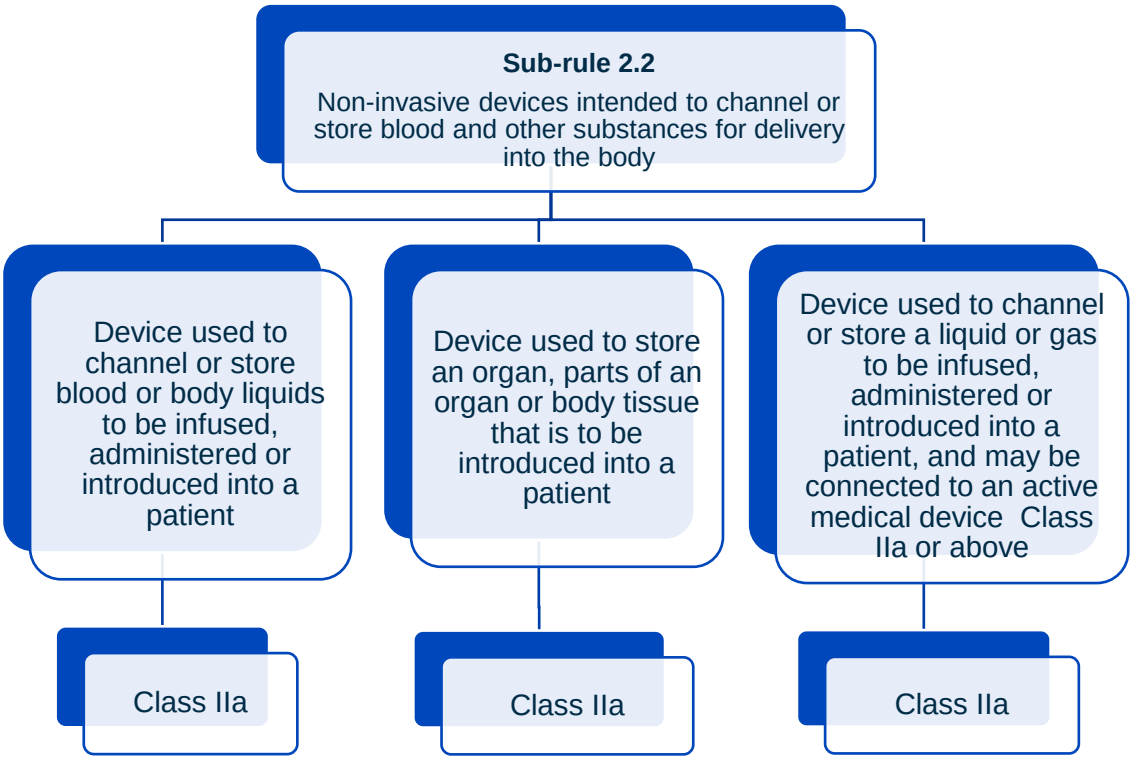
- urine collection bottles
- ostomy pouches
- wound drainage collection bottles.
- Sub-rule 2.1 also covers devices used to immobilise body parts or to apply force or compression, such as:
- dressings
- plaster bandages
- cervical collars
- gravity traction devices
- compression hosiery.



Sub-rule 2.2: Channel or store blood and other substances for delivery into the body

Sub-rule 2.2 states that devices meeting the following descriptions are **Class IIa**.

- **2.2(1)(a):** A non-invasive device used to channel or store blood or body liquids that are to be infused, administered or introduced into a patient**.**
- This includes devices intended to be used to channel active drug delivery systems, such as:
- intravenous tubing
- gastrostomy tubing
- anaesthesia breathing circuits
- pressure indicators and syringes for infusion pumps.
- **2.2(1)(b):** A non-invasive device to store an organ, parts of an organ or body tissue that is to be later introduced into a patient**.**
- This includes devices intended to be used for:
- temporary storage and transport of organs for transplant
- long-term storage of biological substances and tissues such as corneas, sperm or human embryos.
- **2.2(1)(c):** A non-invasive device to channel or store a liquid or gas that is to be infused, administered or introduced into a patient, and may be connected to an active medical device classified as Class IIa or higher.
- This includes devices such as:
- syringes and tubing for infusion pumps
- oxygen tubing and masks
- anaesthetic tubing and breathing circuits.

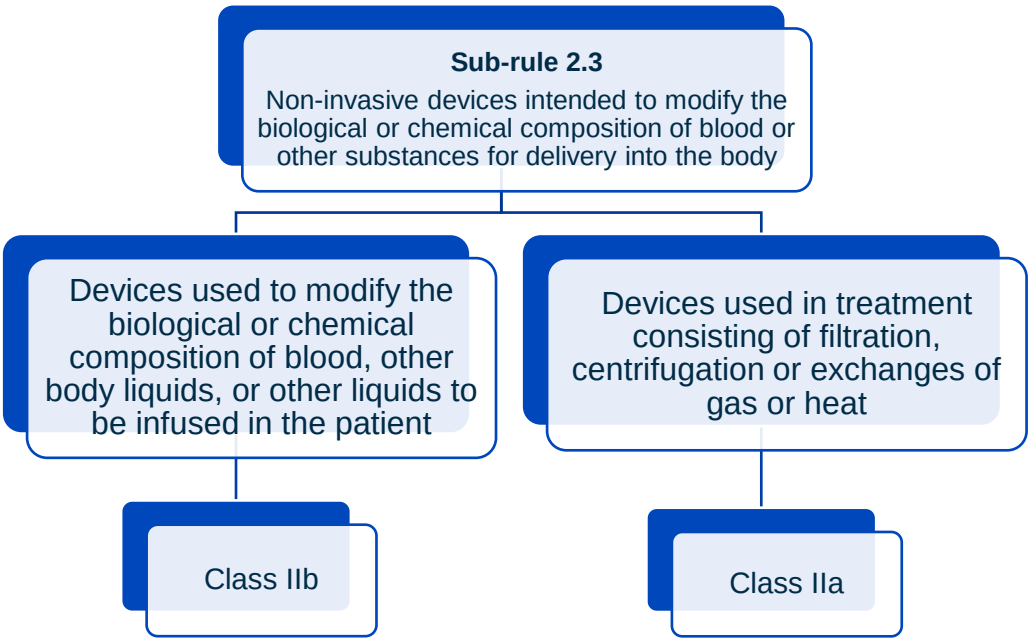


Sub-rule 2.3: Modify the biological or chemical composition of blood or other substances for delivery into the body

Devices in this category must be considered separately from those covered by Rule 2.2, as they treat or modify substances that will be delivered into the body.

Sub-rule 2.3 states that:

- **2.3(1):** Non-invasive devices used to modify the biological or chemical composition of blood, other body liquids, or other liquids to be infused in the patient are **Class IIb**.
- Examples include:
- auto-transfusion systems
- devices used to separate cells such as gradient medium for sperm
- devices intended to remove undesirable substances from blood by exchange of solutes, such as haemodyalisers.
- **2.3(2):** Non-invasive devices used in treatment consisting of filtration, centrifugation or exchanges of gas or heat are **Class IIa**.
- Examples include:
- particulate filtration of blood in an extracorporeal circulation system
- centrifugation of blood for transfusion or auto-transfusion
- removal of carbon dioxide from the blood and/or adding oxygen
- warming or cooling blood in the extracorporeal circulatory system.



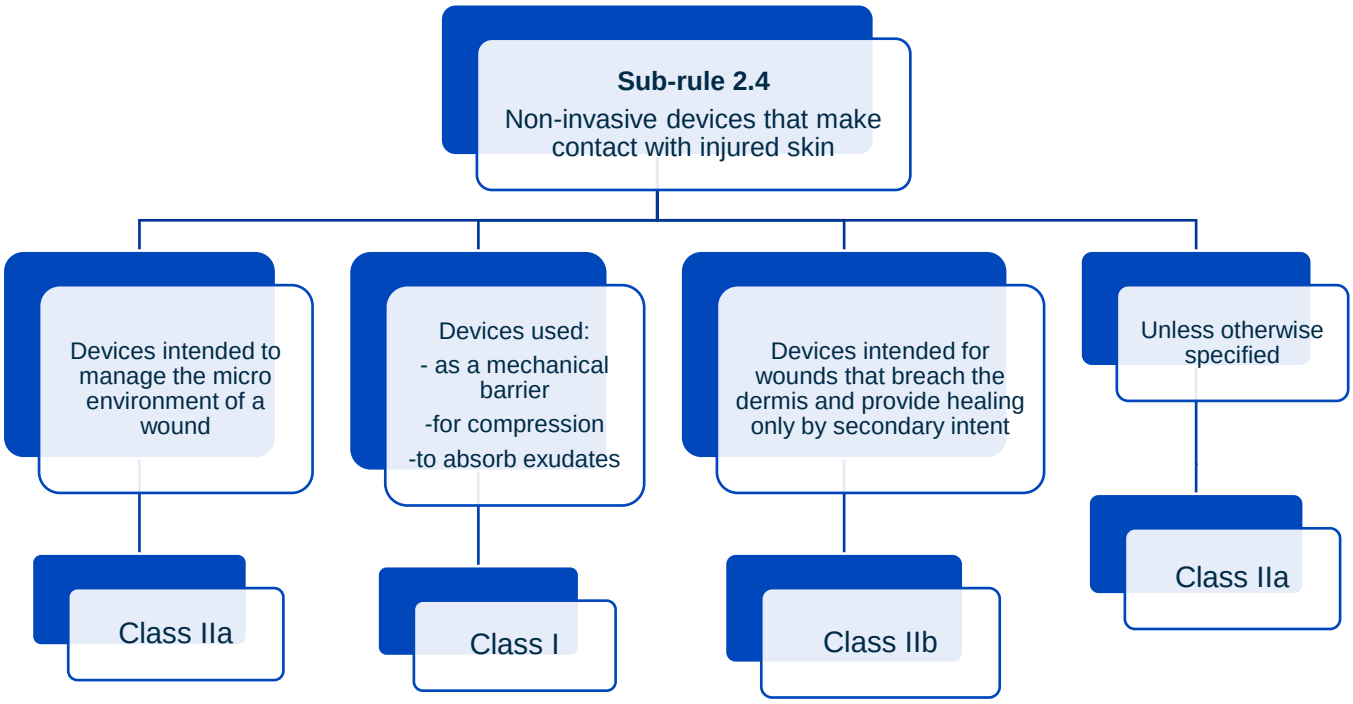
Sub-rule 2.4: Contact injured skin

Sub-rule 2.4 states that:

- **2.4(1):** Non-invasive devices used in contact with injured skin (including devices with the principal intention of managing the microenvironment of a wound) are **Class IIa**. This includes devices that assist healing by controlling the level of moisture and regulating the humidity, temperature, levels of oxygen, other gases and pH values of the wound environment, or by influencing the process by other physical means.
- Examples include:
- adhesives for topical use
- non-medicated impregnated gauze dressings.
- **2.4(3):** Non-invasive devices used as a mechanical barrier or for compression or for absorption of exudates are **Class I**.
- Examples include:
- absorbent pads
- island dressings
- cotton wool
- wound strips and gauze dressings intended to act as a barrier to, or absorb exudates from, a wound.
- **2.4(4):** Non-invasive devices used for wounds that have breached the dermis and where the wounds can only heal by secondary intent are **Class IIb**.
- Examples include:
- dressings for:
  - chronic extensive ulcerated wounds
  - severe burn

  - severe decubitus wounds
- dressings providing a temporary skin substitute.

The decision tree below summarises the rules described in Schedule 2, Part 2 of the MD Regulations.



Rule 3: Invasive

As with the previous rule there are four sub-rules related to invasive medical devices.

Each sub-rule has its own decision tree showing how to apply them when classifying your medical device.

Sub-rule 3.1: intended to be used to penetrate body orifices

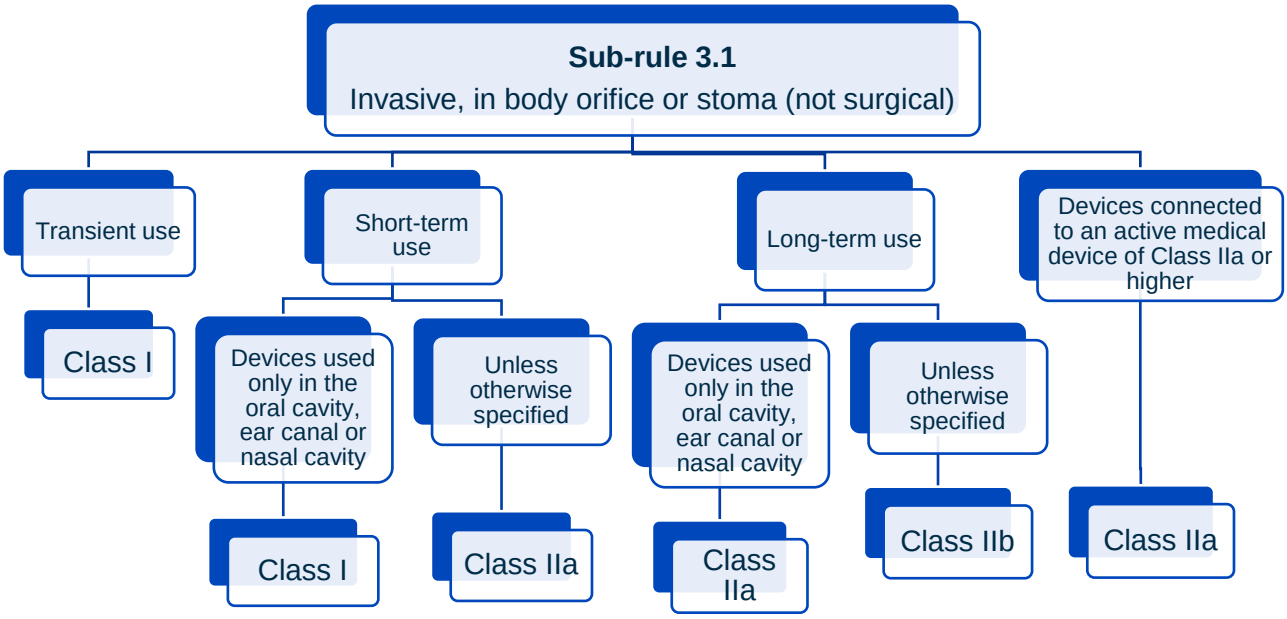
This rule covers devices that enter the body through existing body orifices (for example, the ear, mouth, nose or eye), and devices that are surgically created stomas.

Devices covered by this rule tend to be for diagnostic and therapeutic use in particular specialities: ear, nose, and throat; ophthalmology; dentistry; proctology; urology; and gynaecology.

Sub-rule 3.1 states that:

- **3.1(2)(a):** Invasive devices that are not connected to an active medical device are **Class I**.
- These include:
- handheld dental mirrors
- dental impression materials
- examination gloves
- prostatic balloon-dilation catheters.
- **3.1(2)(b)(i):** Invasive devices that are for short-term use are **Class IIa**.

- These include:
- contact lenses
- urinary catheters
- tracheal tubes
- stents
- vaginal pessaries
- perineal reduction devices.
- **3.1(2)(b)(ii):** Invasive devices that are for short-term use in the oral cavity as far as the pharynx, in an ear canal to the ear drum, or in a nasal cavity, are **Class I**.
- These include:
- dressings for nose bleeds
- dental bite registration wax
- otoscopes that are not active medical devices.
- **3.1(2)(c)(i):** Invasive devices that are for long-term use are **Class IIb**.
- These include:
- long-term urinary catheters
- urethral stents.
- **3.1(2)(c)(ii):** Invasive devices that are for long-term use in the oral cavity as far as the pharynx, in an ear canal to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, are **Class IIa**.
- These include:
- orthodontic wire
- dentures
- retainers
- aligners that are intended to be used for longer than 30 days
- fixed dental prostheses, including palate expanders, Herbst appliances and bonded dental retainers
- fissure sealants.
- **3.1(3):** Invasive devices that are to be connected to an active medical device, which is classified as Class IIa or higher, are **Class IIa**.
- These include:
- powered nasal irrigators
- heat and moisture exchangers
- suction catheters or tubes for stomach drainage.



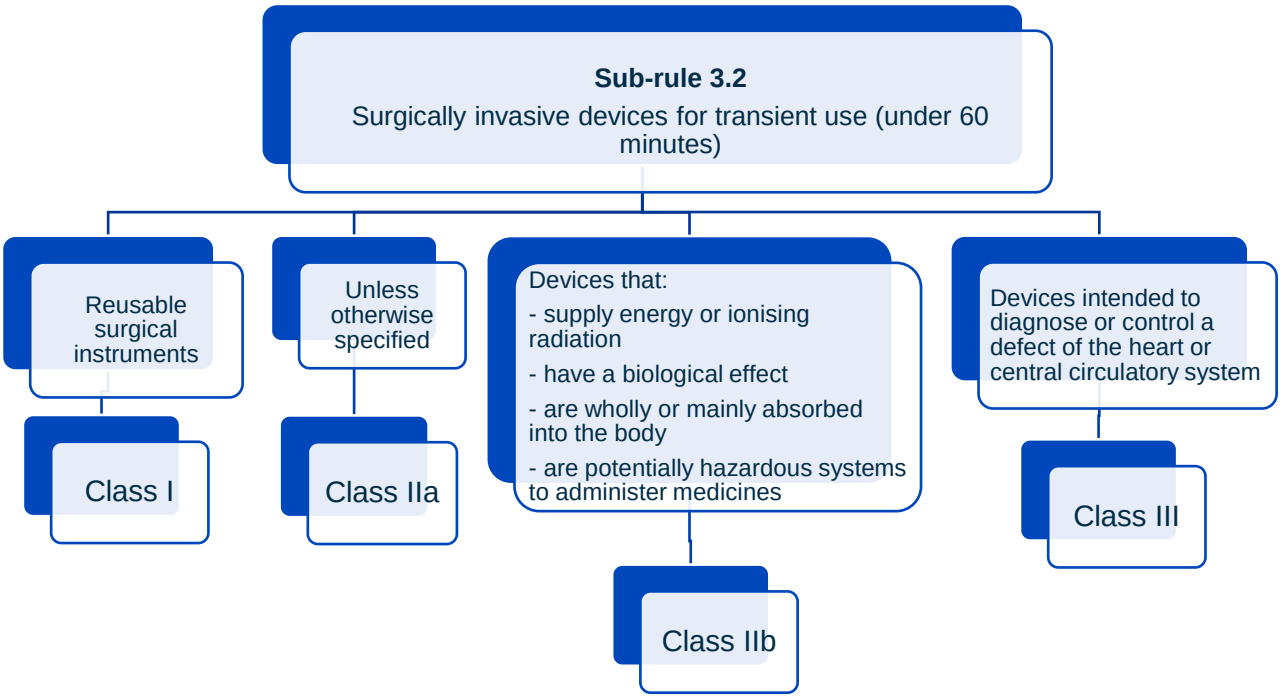
Sub-rule 3.2: Transient use

This rule covers devices that are used to create a conduit through the skin (needles and cannulae), surgical instruments like scalpels and saws, and various types of catheters and suckers, where any of these are intended for transient use (less than 60 minutes).

Sub-rule 3.2 states that:

- **3.2(2):** Surgically invasive devices for transient use are **Class IIa**.
- These include:
- suture needles
- hypodermic needles and syringes
- suckers
- surgical swabs
- surgical gloves
- 3D-printed surgical guides used to place an orthopaedic implant.
- **3.2(3):** Surgically invasive devices for transient use to diagnose, monitor, control or correct a defect of the heart or central circulatory system through direct contact are **Class III**.
- These include:
- cardiovascular catheters
- angioplasty balloon catheters
- coronary artery probes.
- **3.2(3A):** Non-reusable surgical instrument devices specifically to be used in direct contact with the heart, the central circulatory system (CCS) or the central nervous system (CNS) of a patient are **Class III**.

- These include:
- flexible fibreoptic neuroscopes and rigid neuroscopes
- automatic cranial perforators
- spinal needles
- self-expanding valve prostheses
- post-dilatation balloon catheters
- cardiopulmonary cannulae for transient-use.
- **3.2(4):** A reusable surgical instrument is **Class I**.
- These include:
- scissors
- artery forceps
- tissue forceps
- tissue clamps
- excavators
- osteotomes
- chisels.
- **3.2(5)(a):** Surgically invasive devices for transient use to supply ionising radiation are **Class IIb**.
- These include:
- catheters containing or incorporating radioactive isotopes where the isotope is not intended to be released into the body.
- **3.2(5)(b):** Surgically invasive devices for transient use to have a biological effect are **Class IIb**
- **3.2(5)(c):** Surgically invasive devices for transient use to be wholly or mostly absorbed by the body are **Class IIb**.
- These include:
- bone wax.
- **3.2(5)(d):** Surgically invasive devices for transient use to administer medicine via a delivery system, where the administration is potentially hazardous to the patient, are **Class IIb**.
- These include:
- devices for repeated self-application where the dose and the medicine are critical, such as non-pre-filled personal insulin injectors (or ‘pens’).



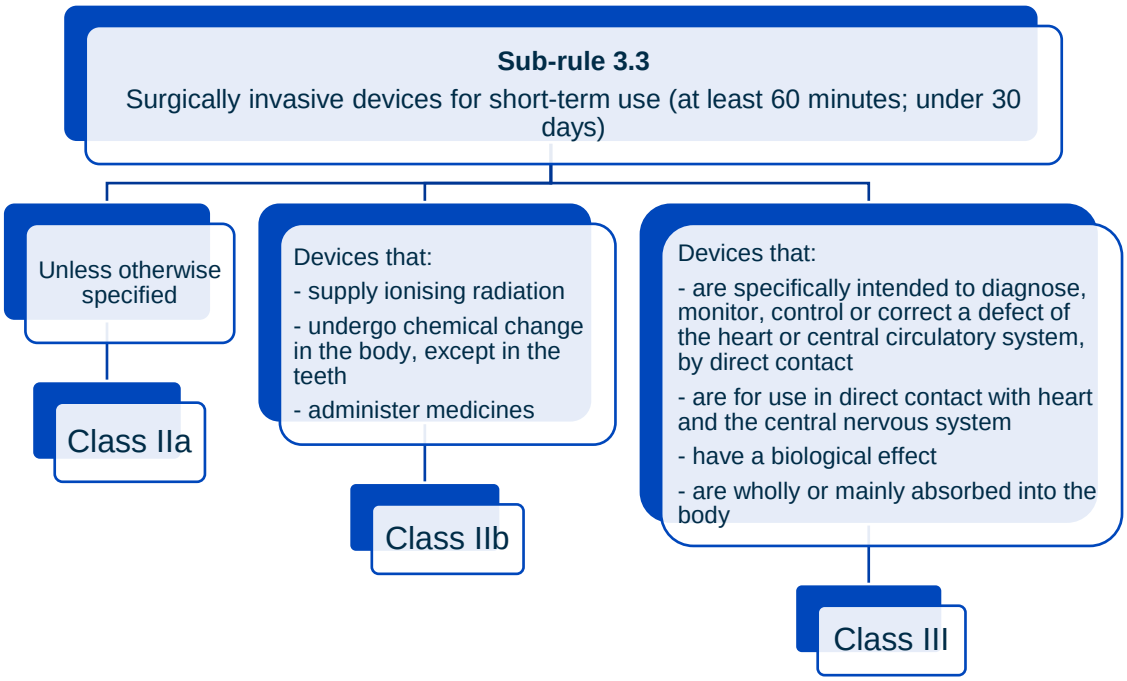
Sub-rule 3.3: Short-term use

This rule covers devices to be used in the context of surgery or post-operative care (for example, clamps and drains), infusion devices (cannulae and needles), and catheters of various types, where any of these are intended for short-term use (continuously for at least 60 minutes but not more than 30 days).

Sub rule 3.3 states that:

- **3.3(2):** Surgically invasive devices for short-term use are **Class IIa**.
- These include:
- clamps
- infusion cannulae
- skin closure devices and temporary filling materials
- chest retractors for cardiac surgery
- some surgical retractors.
- **3.3(3)(a):** Surgically invasive devices for short-term use to supply ionising radiation are **Class IIb**.
- These include:
- bradytherapy devices.
- **3.3.(3)(b):** Surgically invasive devices for short-term use to undergo a chemical change in a patient's body (except for devices intended to be placed in the teeth) are **Class IIb**.
- These include:
- tissue adhesives.
- **3.3(3)(c):** Surgically invasive devices for short-term use to administer medicine are **Class IIb**.

- These include:
- intravenous cannula.
- **3.3(4)(a):** Surgically invasive devices for short-term use to be specifically used to diagnose, monitor, control or correct a defect of the heart or central circulatory system, through direct contact with these parts of the body, are **Class III**.
- These include:
- cardiovascular catheters
- cardiac output probes and temporary pacemaker leads
- thoracic catheters intended to drain the heart, including the pericardium
- carotid artery shunts.
- **3.3(4)(b):** Surgically invasive devices for short-term use to be used in direct contact with the heart and central nervous system are **Class III**.
- These include:
- neurological catheters
- cortical electrodes
- connonoid paddles.
- **3.3(4)(c):** Surgically invasive devices for short-term use to have a biological effect are **Class III**.
- These include:
- haemostatic sponges.
- **3.3(4)(d):** Surgically invasive devices for short-term use to be wholly or mostly absorbed by a patient's body are **Class III**.
- These include:
- absorbable sutures.
- **3.3(5):** Surgically invasive devices for short-term use that are intended by the manufacturer to be placed in the teeth—including devices that are intended to penetrate a tooth, but do not enter the gum or bone beyond the tooth and are intended to undergo a chemical change in the body—are **Class IIa**.
- These include:
- dental adhesives used for root canal therapy.



Sub-rule 3.4: Long-term use

Devices covered by this rule include implants used in the orthopaedic, dental, ophthalmic, and cardiovascular fields. In addition, soft-tissue implants used in plastic surgery are covered by this rule.

Sub-rule 3.4 states that:

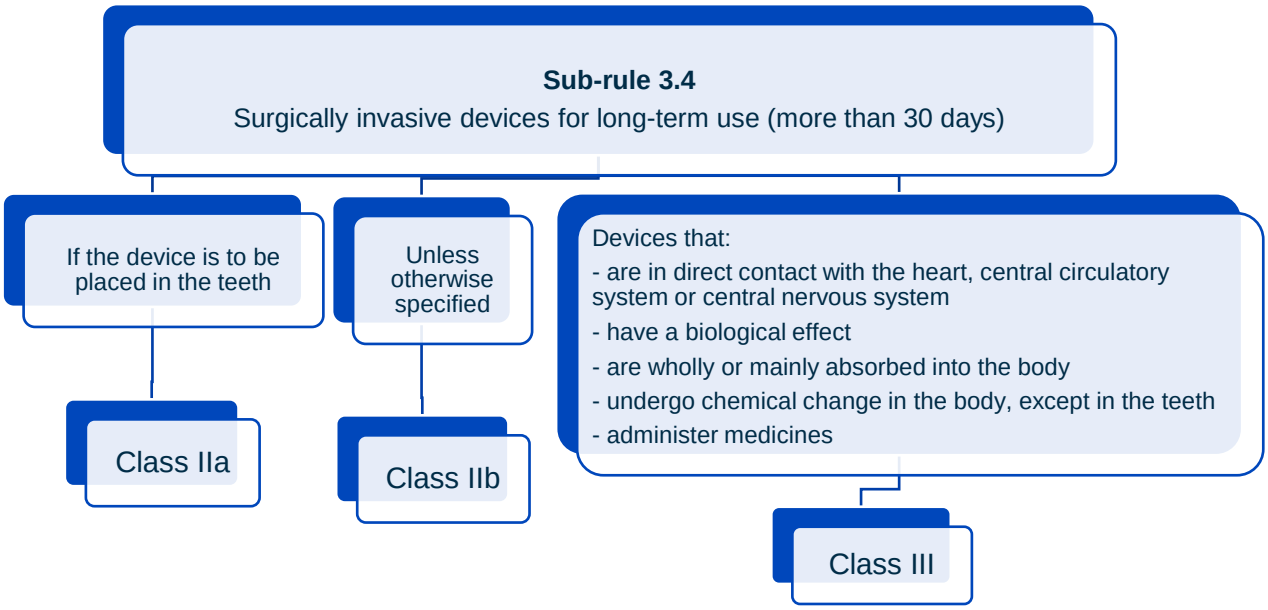
- **3.4(2)**: Surgically invasive devices for long-term use and implantable devices are **Class IIb**.
- These include:
- shunts, stents, nails, plates and screws
- intra-ocular lenses
- infusion ports
- peripheral vascular grafts
- some bone cements (others may be **Class III**, depending on intended purpose and whether it contains a medicine or material of animal origin).
- maxillo-facial implants where there is no contact with the central nervous system
- dental implants
- dental implant abutments
- orthodontic temporary anchorage devices, otherwise known as mini screws
- endosseous implants (non-medicated).
- **3.4(3):** Surgically invasive devices for long-term use to be placed in the teeth are **Class IIa**.
- These include:
- root-canal filling material such as gutta percha.
- **3.4(4)(a):** Surgically invasive devices for long-term use to be used in direct contact with the heart, the central circulatory system or the central nervous system are **Class III**.

- These include:
- prosthetic heart valves
- aneurysm clips
- vascular prostheses
- spinal stents
- vascular stents
- central nervous system electrodes
- cardiovascular sutures.
- **3.4(4)(b):** Surgically invasive devices for long-term use and intended by the manufacturer to have a biological effect are **Class III**.
- **3.4(4)(c):** Surgically invasive devices for short-term use to be wholly or mostly absorbed by a patient's body are **Class III**.
- These include:
- absorbable sutures
- bioactive adhesives
- implants through the attachment of surface coatings such as phosphorylcholine.
- **3.4(4)(d):** Surgically invasive devices for long-term use to undergo a chemical change in the patient's body (except devices that are to be placed in the teeth) are **Class III**.
- These include:
- surgical adhesives.
- **3.4(4)(e):** Surgically invasive devices for long-term use to administer medicine are **Class III**.
- These include:
- rechargeable non-active drug delivery systems.

See Boundary and combination products.

- **3.4(5):** Surgically invasive devices for long-term use that are intended by the manufacturer to be placed in the teeth—including devices that are intended to penetrate a tooth but do not enter the gum or bone beyond the tooth—and are intended to undergo a chemical change in the body, are **Class IIa**.
- These include:
- dentine adhesives.

For the purposes of this rule, *placed in the teeth* means the device is intended to penetrate a tooth, but does not enter the gum or bone beyond the tooth.



Sub-rule 3.4A: Joint-replacement devices and surgical meshes

Devices covered by this rule include joint replacements used in orthopaedic fields as well as surgical meshes.

Sub-rule 3.4A states that:

- Joint replacement medical devices are **Class III**.
- These include:
- implantable shoulder, hip- and knee-joint replacement medical devices and ancillary medical devices.

See Defining joint replacement medical devices and ancillary medical devices.

- Devices that are surgical meshes are **Class III**.
- These include:
- hernia surgical mesh
- urogynaecological surgical mesh (most commonly indicated for pelvic organ prolapse and stress urinary incontinence)
- male slings (for stress urinary incontinence)
- surgical mesh used in orthopaedic and trauma reconstructive surgeries
- synthetic or biological surgical mesh patches used in plastic and reconstructive surgery
- abdominal plugs made from mesh.

For the purposes of this rule, *surgical meshes* does not include mesh-like implants used for the compensation of bone loss or repair of structural bone defects, such as acetabulum cages, cranial mesh, or mesh used in the repair of facial (mandibular or zygomatic) bones.

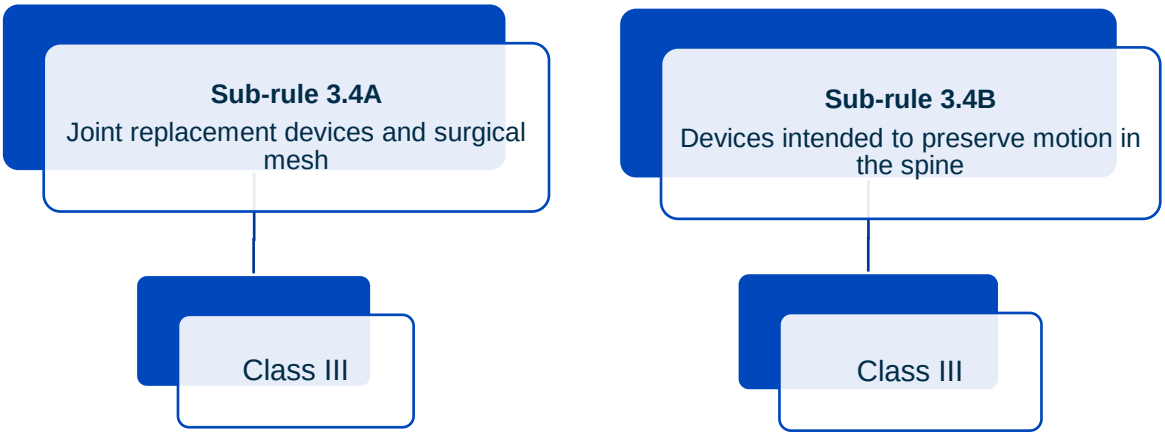
See Reclassification of surgical mesh devices.

Sub-rule 3.4B: Motion preserving devices for the spine

Devices covered by this rule are those intended to be used to preserve motion in the spine. These devices are **Class III.**

These include:

- artificial spinal disc replacements
- anatomic facet replacement systems
- interspinous process spacers.



Rule 4: Active

An active medical device is a device that—to operate—uses and converts energy in a significant way.

An active medical device may use any form of energy except for gravitational or direct human energies. Active medical devices may run from internal or external power sources.

Devices that incorporate software, or that are software, are active medical devices. There are additional specific rules that must be considered when classifying these devices.

Rule 5: Rules for particular kinds of devices

There are multiple sub-rules that apply to specific kinds of devices as described in Schedule 2, Part 5 of the Regulations.

Each sub-rule has its own decision tree showing how to apply them when classifying your medical device.

Sub-rule 5.1: Contain a medicine

This rule covers medical devices that incorporate a medicinal substance including stable derivatives of human blood and blood plasma that assists the function of the device.

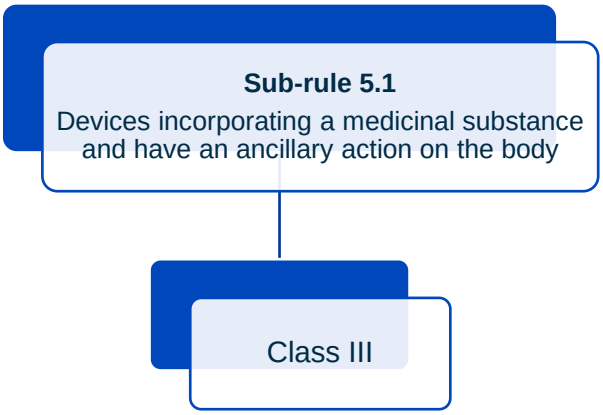
Sub-rule 5.1(2) states that devices incorporating a substance that, if used separately, would be a medicine, and that have an ancillary action on the body, are **Class III**.

These include:

- bone cements with antibiotic
- condoms with spermicide
- heparin-coated catheters

- dressings incorporating an antimicrobial agent where the purpose of such an agent is to provide ancillary action on the wound
- catheters coated with an anticoagulant or an antibiotic agent
- coronary artery stents coated with a medicine (for example, drug-eluting stents)
- sponge impregnated with antibiotics
- intraocular viscous solution with anaesthetic
- medicated root canal sealant
- silver-impregnated dressings
- surgical adhesive of collagen (medical device) and thrombin (medicine) packaged as two components that are applied to the patient after being mixed together.

For the purposes of this sub-rule, a *medicine* includes any stable derivative of human blood or human plasma.



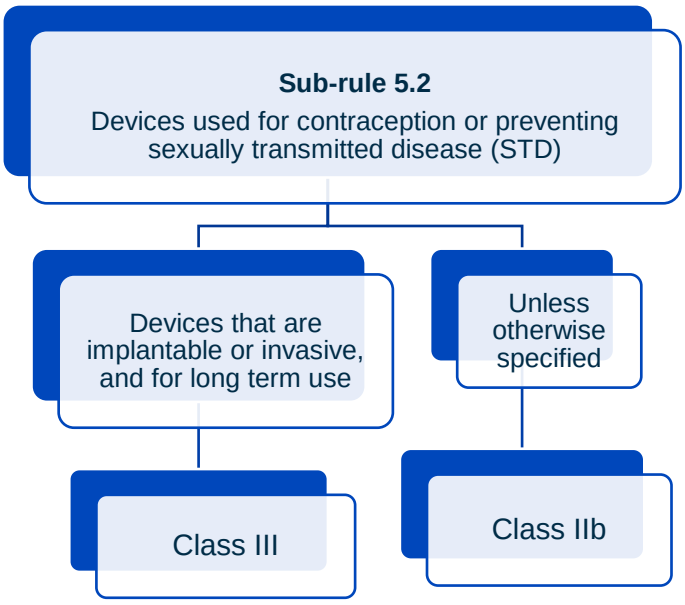
See Boundary and combination products

Sub-rule 5.2: Contraception or STD prevention

Some devices covered by this rule, such as condoms, may perform both functions.

Sub-rule 5.2 states that:

- **5.2(1):** Devices for contraception or the prevention of sexually transmitted diseases are **Class IIb.**
- These include:
- condoms
- contraceptive diaphragms.
- **5.2(2):** Implantable or invasive devices intended for long-term use (continuously for more than 30 days) are **Class III**.
- These include:
- contraceptive intrauterine devices (IUDs) that are not hormone-eluting
- surgically implanted contraceptive devices.



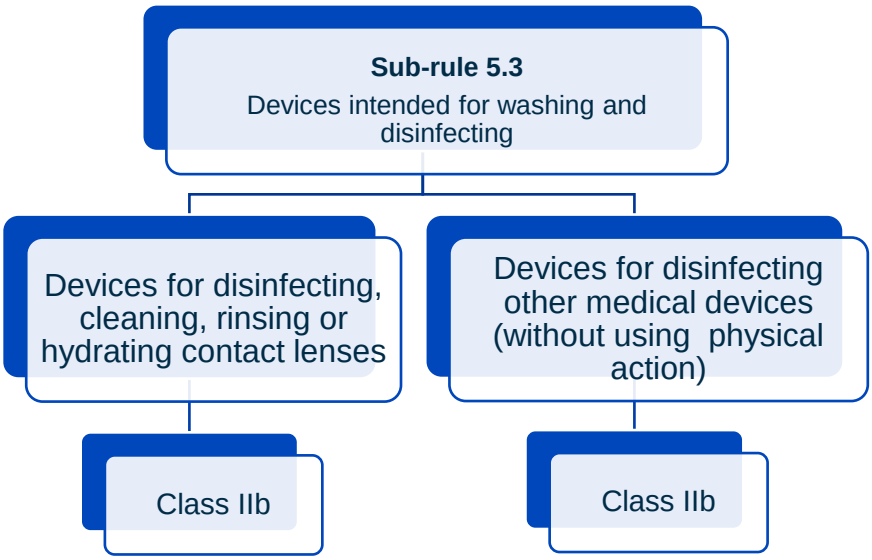
Sub-rule 5.3: Washing and disinfecting

This rule covers various contact lens fluids, and substances or equipment intended to be used to disinfect another medical device. It does not cover devices that clean by a physical action only.

Sub-rule 5.3 states that:

- **5.3(1):** Devices specifically for disinfecting, cleaning, rinsing or hydrating contact lenses are **Class IIb**.
- These include:
- contact lens solutions and comfort solutions.
- **5.3(2):** Devices specifically for disinfecting other medical devices are **Class IIb**.
- These include:
- disinfectants for haemodialysis devices and endoscopes
- sterilisers to sterilise medical devices
- washer disinfectors.

This clause does not apply to a medical device that is intended only to clean another medical device (other than contact lenses) by means of physical action – these devices are **Class I** (see Rule 2.1).

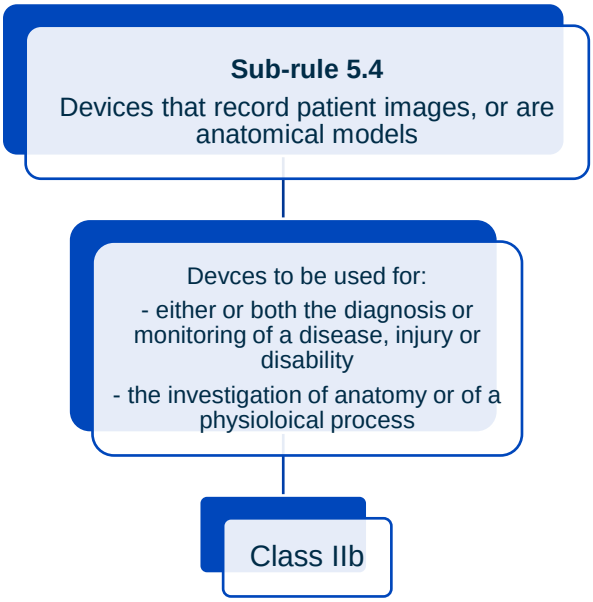


Sub-rule 5.4: Used in patient imaging and anatomical models

Sub-rule 5.4 states that devices covered by the following descriptions are all **Class IIa**:

- **5.4(1):** A device that is intended to record patient images that are to be used for either or both of the diagnosis and monitoring of a disease, injury or disability; and the investigation of the anatomy or of a physiological process; and the images are to be acquired through a method that relies on energy outside the visible spectrum.
- These include:
- a magnetic resonance imaging (MRI) machine intended to record images for the purpose of detecting torn ligaments in a patient
- software intended to record images of soft-tissue injury captured from an ultrasound imaging device
- spinal analysis machine used to record, display and analyse medical images to support treatment planning
- software that displays medical images of the spine to support treatment planning.
- **5.4(2):** An anatomical model (whether physical or virtual) to be used for either or both of the diagnosis or monitoring of a disease, injury or disability; or the investigation of the anatomy or of a physiological process.
- These include:
- a 3D-model of the myocardium for identifying ventricular septal defects
- a 3D-model-producing photogrammetry smartphone app intended to be used by an orthotist, taking photos of an infant's head, to help gauge the effectiveness of cranial orthoses in the treatment of plagiocephaly
- a 3D-model produced from magnetic resonance imaging (MRI) scan data intended to help a surgeon to plan complex facial reconstruction surgery.
- **5.4(3):** A device to be used to generate a virtual anatomical model that is to be used for either or both of the diagnosis or monitoring of a disease, injury or disability; and the investigation of the anatomy or of a physiological process.
- These include:

- software that is intended to generate a 3D-anatomical virtual model from patient scans for the purpose of a health professional diagnosing a stress fracture.



Rule 5.4 vs other diagnosing and monitoring rules

Many of the devices captured by Rule 5.4 will also be captured by Rules 4.3, 4.5, and 4.6. When more than one rule applies, the device is classified according to the higher resulting Class. See Classification of active medical devices.

Sub-rule 5.5: Containing non-viable animal tissues or their derivatives

This rule covers devices that contain or are made of animal tissues that have been rendered non-viable, or derivatives from such tissues that are also non-viable, or microbial or recombinant tissues, cells or substances.

Sub-rule 5.5 states that:

- **5.5(1)(a):** Devices that contain animal tissues or derivatives that have been rendered non-viable are **Class III**.
- These include:
- biological heart valves
- porcine xenograft dressings
- catgut sutures
- implants and dressings made from collagen.
- This sub-rule does not apply to a device that only contains animal tissues that have been rendered non-viable and where the device is only intended by the manufacturer to come into contact with intact skin (for example, leather straps associated with limb prostheses).
- **5.5(1)(b):** Devices that contain tissues, cells or substances of microbial or recombinant origin are **Class III**, even if the device is only intended to come into contact with intact skin.
- These include:

- intra-ocular fluids
- meniscal joint fluid replacement
- anti-adhesion barriers
- tissue fillers based on hyaluronic acid derived from bacterial fermentation processes.

Tissues and cells that have been *rendered non-viable* are ones that have been processed to a point such that no further inherent capacity for cellular metabolic activity exists.

Therapeutic goods that comprise or contain live animal cells, tissues or organs are regulated as biologicals.

Sub-rule 5.5 covers medical devices in which animal tissues, cells and their derivatives are used as:

- raw and starting materials, such as collagen, hyaluronate and gelatin.
- active substances, like heparin.
- excipients in the device, such as bovine serum albumin
- reagents used in production, such as porcine pepsin, albumin or meat broth used in the culture of microbial cell lines.

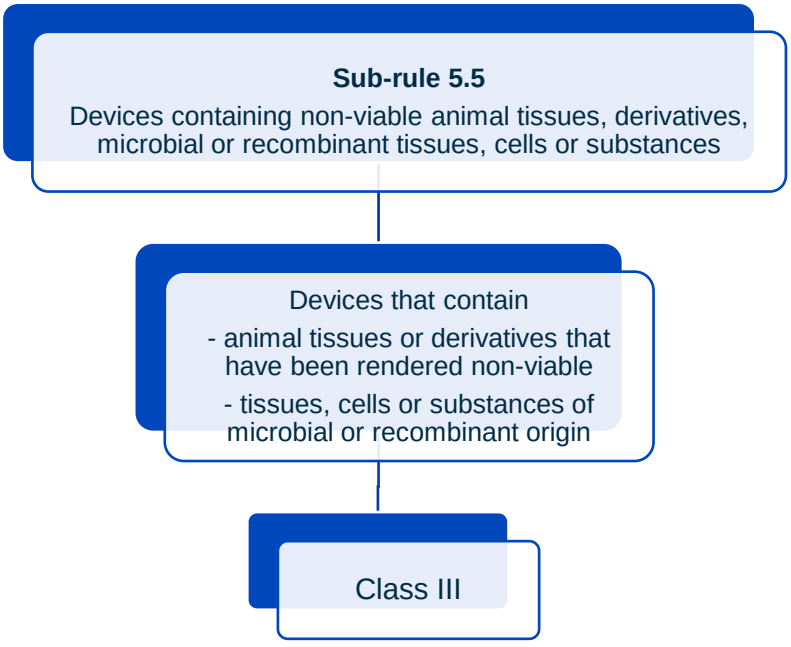
Sub-rule 5.5 also covers medical devices that contain tissues, cells or substances of:

  – microbial origin (produced through a process like biofermentation, harvested from a microbial cell-culture, or in the finished product itself)

  – recombinant origin (from any category of genetically modified organism, either during manufacturing or in the finished product).

For more on this sub-rule, contact the TGA at <devices@tga.gov.au> or on 1800 141 144.

- Honey is not considered to be an animal-derived substance for the purposes of the classification rules.

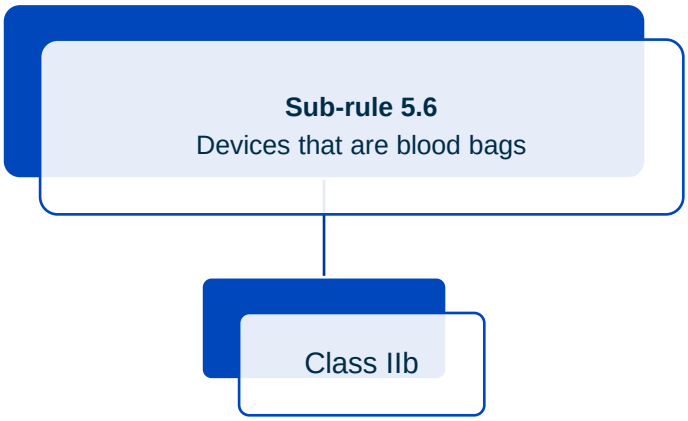


Sub-rule 5.6: Blood bags

Sub-rule 5.6 states that medical devices that are blood bags are **Class IIb**.

These include devices containing or coated with an anticoagulant.

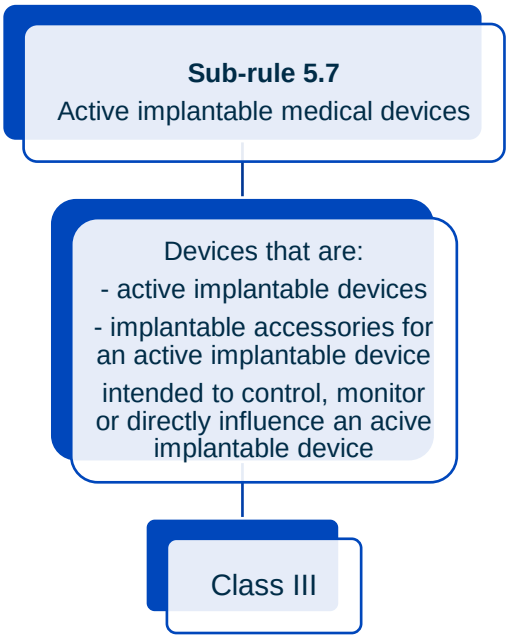
If a blood bag has a function greater than storing purposes, and includes systems for preservation other than anti-coagulants, then other rules (such as sub-rule 5.1) may apply.



Sub-rule 5.7: Active implantable

This rule covers active medical devices that are implantable. When referring to a medical device, the term active means that the device depends on a source of energy (other than human generated or gravitational) to operate and acts by converting this energy.

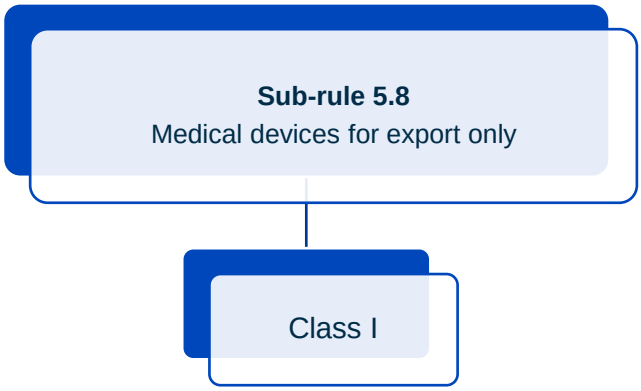
Implantable accessories for these active implantable devices, as well as devices intended to control, monitor or directly influence an active implantable device are also covered by this rule.



Sub-rule 5.8: For export only

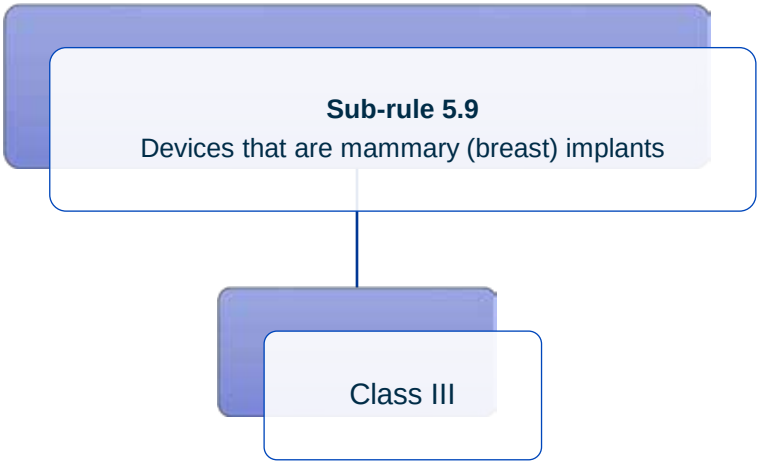
Medical devices intended by the manufacturer for export only are **Class I**.

This is a special rule. Devices intended for export only are *always* Class I. See Export of medical devices.



Sub-rule 5.9: Mammary (breast) implants

Medical devices that are mammary implants are **Class III**.



Sub-rule 5.10: Administered by inhalation

This rule covers devices intended to administer medicines or biologicals by inhalation.

These include devices that are widely used for the treatment of respiratory disorders, such as:

- asthma
- obstructive lung disorder
- cystic fibrosis
- pulmonary arterial hypertension
- infectious pulmonary disease.

More recently, the clinical use of aerosols has expanded to non-respiratory conditions, such as diabetes, analgesia, thyroid disorders, and genetic diseases.

When determining the classification of a device, manufacturers should consider these questions:

- Does the mode of action (for example, action, mechanism, or operation) of the device have a bearing on the delivery, dosage, efficacy, or safety of the medicine or biological that is being delivered to the person? For example, if a nebuliser failed to effectively aerosolise a medicine for inhalation by a patient, this would affect the efficacy of the medicine.

- ü If the answer to the question is yes, the device is **Class IIb**.

- Is the device intended to administer a medicine or biological by inhalation to treat a life-threatening condition, where, if the operation of the device failed, it could result in the death of the person?

- For example, if a medical device failed to effectively deliver medication to a patient to treat a severe asthma attack, it could result in the death of the person.

- ü If the answer to the question is yes, the device is **Class IIb**.

See Boundary and combination products.

Sub-rule 5.10

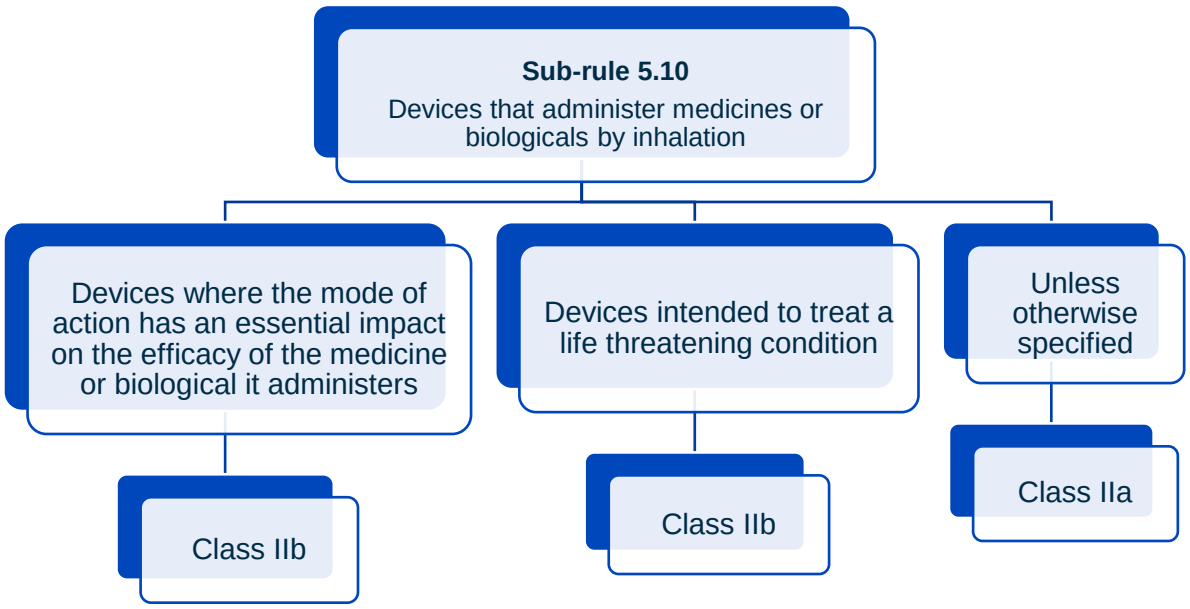
5.10(a): Devices *if the mode of action of the device has an essential impact on the efficacy and safety of the medicines or biologicals*—Class IIb.

Example: Nebuliser

5.10(b): Devices *if the device is intended to treat a life-threatening condition—Class IIb*.

Example: Endotracheal tube

5.10(c): *if paragraphs (a) and (b) do not apply—Class IIa.*



Sub-rule 5.11: Substances introduced into the body or absorbed by the skin

This sub-rule covers devices that are composed of substances, or combinations of substances, that are introduced into the human body through an orifice or applied to and absorbed by the skin.

Classification of these devices can be **Class IIa or IIb** depending on where and how they achieve their intended purpose.

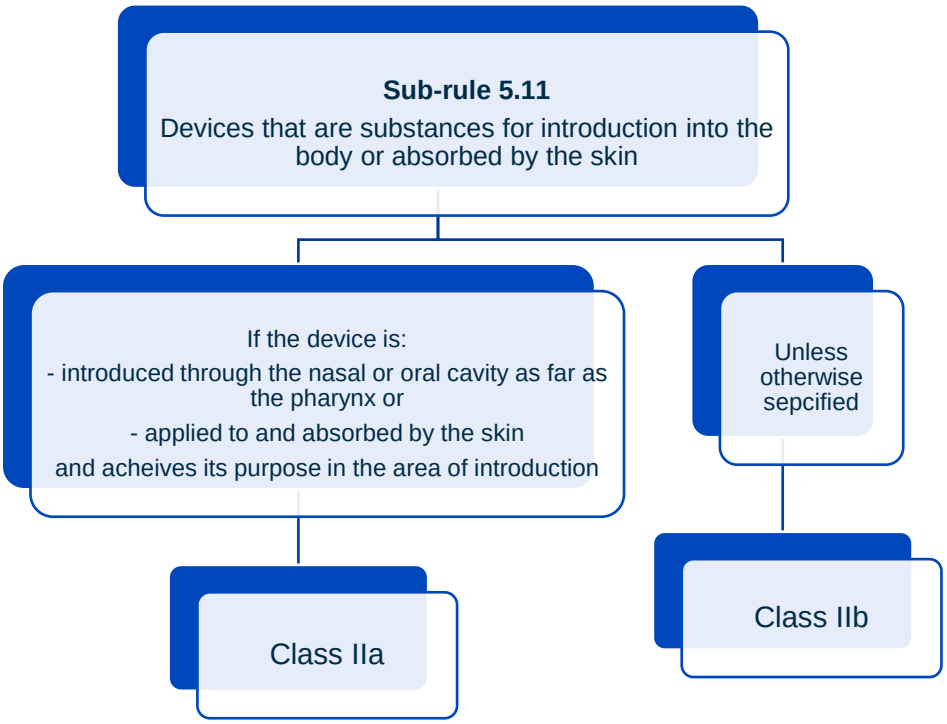
Examples could include the following products:

- isotonic saline solution nasal sprays

- non-medicinal lozenges that only exert their effect in the mouth cavity
- some wart removers (not intended to achieve their action by pharmacological, immunological, or metabolic means)
- gels for vaginal discomfort (not including anti-fungal or antimicrobial chemicals)
- wound protection gels and creams (that are absorbed but are not medicines) to treat or prevent minor skin irritations
- weight loss capsules that expand in the stomach to create a feeling of satiety and are do not achieve their action in the body by pharmacological, immunological or metabolic means
- products for topical use such as creams, gels, or ophthalmic solutions (for example, eye lubricants that do not contain a medicine).

We consider dyes and stains for diagnostic purposes to be medicines, such as for identification of a corneal lesion or a sentinel lymph node.

We consider dyes and stains for identification of normal anatomy that do not contain a medicine to be devices (for example, surgical marker pens).



Many therapeutic substances are medicines or other types of therapeutic good (that is, not medical devices).

This sub-rule only applies to those products composed of substances or of combinations of substances that **meet the definition of a medical device.**

See Boundary and combination products

Case studies

The following examples are provided to demonstrate the importance of considering all the classification rules when classifying your medical device.

The examples do not include all the possible devices that may be on the market—they are intended only to demonstrate how different variables can affect the classification of a device.

There may be several classification rules that apply to your device—if this happens the highest classification applies, with the exception of medical devices for export only (Rule 5.8), which are classified as Class I.

Case study 1: Dressings

Intended purpose: *To be applied to a wound to promote healing and to prevent further harm*.

Table 2: Examples of different dressings and the different rules and classes that can apply

Description	Variable/comments	Rule	Class
A negative wound therapy dressing bandage	Used together with an active medical device to manage the microenvironment of a wound.	Rule 2.4(1)	Class IIa
A non-sterile, trauma covering used to maintain the stability of a burn patient en route to a hospital. Dressing is coated in a gel containing anaesthetic	Contains medicine	Rule 5.1(2)	Class III
A non-sterile, trauma covering used to maintain the stability of a full thickness burn patient en route to a hospital. Dressing is coated in a gel that does not contain any active medicine ingredients.	Breached the dermis. Does not contain medicine	Rule 2.4(4)	Class IIb
A wound dressing for deep wounds and ulcers that have breached the dermis containing collagen for wound healing	Contains a substance of animal origin	Rule 5.5(1)(a)	Class III
A hydrogel dressing used to maintain microenvironment of the wound and to act as mechanical barrier.	The inclusion of ‘maintain microenvironment of the wound’ makes this a Class IIa. If the dressing was used solely as a mechanical barrier, then it would be Class I per 2.4(3)(a).	Rule 2.4(1)	Class IIa
A wound dressing including materials of biological origin, such as collagen, chondroitin sulphate	Contains materials of biological origin	Rule 5.5(1)(a)	Class III
Adhesive dressing strip—not sterile	Not sterile	Rule 2.4.3(c)	Class I
Adhesive dressing strip—sterile	Sterile	Rule 2.4.3(c)	Class I (sterile)

Description	Variable/comments	Rule	Class
Adhesive dressing strip—with silver	Has silver (microbial agent) to assist in healing. The silver is a medicine	Rule 5.1 (2)	Class III
Compression bandage used for sprains	Used for compression to assist in injury management	Rule 2.4(3)(b)	Class I

Case study 2: Fixation screws

Intended purpose: To hold plates or nails to bone, fasten soft tissue to bone or provide inter-fragmentary stabilisation for bone.

Table 2: Examples of fixation screws and the different rules and classes that can apply

Description	Variable/comments	Rule	Class
Absorbable fixation screw; permanent implant, absorbed into body	Will be absorbed into body	Rule 3.3(4)(d)	Class III
Fixation screw that has direct contact with central circulatory or central nervous systems	Location in body—direct contact with central circulatory or central nervous systems.	Rule 3.3(4)(a)	Class III
Metal fixation screw used to hold bone together for longer than 30 days	Long-term use Permanently implanted	Rule 3.4(2)	Class IIb
Metal fixation screw—used to hold bone together for up to 30 days (for example, to support healing of a fracture)	Short-term use	Rule 3.3(2)	Class IIa
Metal fixation screw—used to hold bone together temporarily during surgery	Transient use	Rule 3.2(2)	Class IIa

Relevant legislation

- Section 41BD of the *Therapeutic Goods Act 1989* (the Act)
- Regulations 3.2 and 3.3 of the MD Regulations
- Schedule 2 of the MD Regulations
- MD Regulations Dictionary.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication as Section 4 of Australian Regulatory Guidelines for Medical Devices (ARGMD).	Office of Devices, Blood & Tissues	April 2010
V1.1	Update to ARGMD. Made various punctuation and grammar amendments. Reformatted for compliance with new TGA style manual.	Office of Devices Authorisation	May 2011
V2.0	Republished as web content titled *Classification of medical devices that are not IVDs*. New and amended rules added, including incorporation of: • surgical mesh • new rule 5.4 • the 2019 reclassification rules. Active medical device classification guidance removed from this content, as it was republished as separate guidance in October 2021. Associated examples updated. Updated to align with: • new Australian Government Style Manual • TGA Website Redevelopment project • updated guidance template.	Medical Devices Authorisation Branch	July 2024

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