MEDICAL DEVICE CLASSIFICATION IN AUSTRALIA

Therapeutic Group Administration (TGA)

The risk level of medical devices determines their classification. The higher classification level, the tougher the requirements will be.

We classify devices based on:

- What does the manufacturer intend the medical device to be used for?
- How invasive will it be in the body (e.g., is it placed on the skin, or a catheter inserted into the body)?
- Where on (or in) the body will it be used?
- How long will it be used for?

Class	Risk Level
Class I	Low
Class IIa	Low to Medium
Class IIb	Medium
Class III	Medium to High

The classification is conducted in accordance with the classification rules outlined in **Section 2 of the Therapeutic Goods (Medical Devices) Regulations 2002**, consisting of five classification rules.

Rule 1 - 'Transient, short-term, and long-term use': This rule applies to all medical devices. When determining the classification of a medical device, it is essential to consider the intended duration of continuous use.

- 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**.

Rule 2 - 'Non-Invasive ' and 'Non-Active' Devices

Rule 3 - Invasive Devices: This rule is applicable for devices that ***penetrates the body through a body orifice or is inserted into the body during surgery***

Rule 4 - Active Devices: This rule is applicable for devices that ***depends on a source of energy for its operation and converts that energy in a significant way.*** This rule also applies to devices that ***incorporate or are software-based medical devices.***

Rule 5 - Rules for particular kinds of devices

Here are a few examples listed below:

Class I

Non-Invasive Devices


Urinary Collection Bottle


Plaster Bandages


Cervical Collar


Walking Aid


Ostomy Pouch


Compression Hosiery


Absorbent Pads

Invasive Devices


Prostatic Balloon-Dilation Catheters


Dressings for Nose Bleeds


Artery Clamp


Examination Gloves


Excavator


Dental Impression


Handheld Dental Mirror


Osteotomes

Class IIa

Non-Invasive Devices


Anesthesia Breathing Circuit


Gastrostomy Tubing


Oxygen Tubing & Masks


Oxygenator


Hypodermic Syringe

Invasive Devices


Sterile Surgical Gloves


Tracheal Tubes


Dentures


Suture Needles


Infusion Cannulae


Contact Lens

Class IIb

Invasive Devices


Bone wax


Insulin Pen

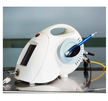

Urethral Stent


Orthopedic Implants

Active Devices


Patient Monitoring Device


Diagnostic X-ray Machine


Surgical Laser


Autotransfusion

Class III

Active - Invasive Devices

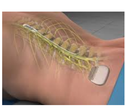

Breast Implants


Absorbable Surgical Suture


Prosthetic Heart Valves


Dental Impants


Cochlear Implant


Spinal Cord Stimulator

Pacemaker

Implantable Cardioverter-Defibrillators