



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

**Australian Medical Devices
Guidance Document
Number 25**

Classification of Medical Devices



January 2005

DISCLAIMER

This document is provided for guidance only. The classification examples provided might vary if a manufacturer assigns a different intended purpose to that used for the examples. Manufacturers and sponsors **must** use the Classification Rules, as contained in the *Therapeutic Goods (Medical Devices) Regulations 2002*, to classify their medical devices.

Please refer to the *Therapeutic Goods Act, 1989* as amended by the *Therapeutic Goods Amendment (Medical Devices) Bill, 2002* and the *Therapeutic Goods (Medical Devices) Regulations, 2002* for legislative requirements.

FURTHER INFORMATION

The Medical Devices Information Unit of the Office of Devices, Blood and Tissues of the Therapeutic Goods Administration (TGA) can be contacted by:

Telephone: 1800 141 144
Facsimile: (02) 6232 8299
Email: cab.medical.device.information@health.gov.au
Website: <http://www.tga.gov.au/devices/devices.htm>
Mail: PO Box 100
Woden
ACT 2606

© Commonwealth of Australia 2005

AMENDMENT SCHEDULE

Version Number	Date of Amendment	Summary of Amendments

CONTENTS

Disclaimer	2
Further Information.....	2
Amendment Schedule.....	3
Introduction	6
Purpose	6
Background	6
The classes of medical devices.....	6
The classification rules	7
Classifying a medical device.....	7
Deciding what classification rules apply.....	7
Important points to remember	8
Flowchart 1- deciding what classification rules apply	9
FLOWCHART 2 CLASSIFICATION RULES - NON INVASIVE DEVICES.....	10
RULE 2 NON INVASIVE MEDICAL DEVICES.....	11
Rule 2.1 Non-invasive medical devices – general	11
Rule 2.2 Non-invasive devices intended to channel or store blood, etc	11
Rule 2.3 Non-invasive devices intended to modify the biological or chemical composition of blood, etc.....	12
Rule 2.4 Non-invasive devices intended to have contact with injured skin	12
FLOWCHART 3 CLASSIFICATION RULES - INVASIVE DEVICES.....	13
FLOWCHART 3A CLASSIFICATION RULES - INVASIVE DEVICES.....	14
RULE 3 INVASIVE MEDICAL DEVICES.....	15
Rule 3.1 Invasive devices intended to be used to penetrate body orifices.....	15
Rule 3.2 Surgically invasive devices intended for transient use	15
Rule 3.3 Surgically invasive devices intended for short-term use	16
Rule 3.4 Surgically invasive devices for long-term use and implantable devices	17
FLOWCHART 4 CLASSIFICATION RULES - ACTIVE DEVICES	18
RULE 4 ACTIVE MEDICAL DEVICES	19
Rule 4.1 Active medical devices – general	19
Rule 4.2 Active medical devices for therapy	19
Rule 4.3 Active medical devices for diagnosis	20
Rule 4.4 Active medical devices intended to administer or remove medicines, etc from a patient’s body.....	20
FLOWCHART 5 CLASSIFICATION RULES –Special rules.....	21
RULE 5 SPECIAL RULES	22
Rule 5.1 Devices incorporating a medicine.....	22
Rule 5.2 Devices for contraception or prevention of sexually transmitted diseases	22

Rule 5.3 Devices intended for disinfecting, cleaning, rinsing etc	22
Rule 5.4 Non-active devices intended to record X-ray diagnostic images	22
Rule 5.5 Devices containing non-viable animal tissues or derivatives	22
Rule 5.6 Devices that are blood bags.....	23
Rule 5.7 Active implantable medical devices	23
Rule 5.8 Medical devices for export only	23
Rule 5.9 Devices that are mammary implants	23
APPENDIX A - Definitions.....	24
Accessory	24
Active implantable medical device	24
Active medical device	24
Active medical device for diagnosis	24
Active medical device for therapy	24
Ancilliary action	25
Biological effect	25
Body orifice	25
Central circulatory system	25
Central nervous system.....	25
Chemical change	25
Direct diagnosis	26
Duration	26
Implantable medical device	26
Integral	26
Intended purpose	26
Invasive medical device	26
Measuring function	26
Medical device	27
Potentially hazardous	27
Reusable surgical instrument	27
Surgically invasive medical device	27
Vital physiological process	28
Wholly or mainly absorbed	28

INTRODUCTION

This guidance document is one of a series produced to assist a wide-ranging audience to understand the regulatory system for medical devices in Australia that commenced on 4 October 2002. The system has been established by the *Therapeutic Goods Act, 1989* and the *Therapeutic Goods (Medical Devices) Regulations, 2002*.

Although each guidance document has been developed to provide information about particular aspect of the medical devices regulatory system in Australia, it is expected that a certain amount of cross-referencing to other documents in the series will be inevitable.

PURPOSE

The purpose of this document is to provide guidance on the classification rules for medical devices and relates to the following segments of the medical device legislation.

- Section 41BD of the *Therapeutic Goods Act 1989* (the Act)
- Regulation 3.2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (MD Regulations).
- Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002*.
- Dictionary – *Therapeutic Goods (Medical Devices) Regulations 2002*.

BACKGROUND

The risks associated with using medical devices can range from little or no risk to patients and users to significant potential risks inherent in the type of device. The level of premarket intervention by the regulator is proportional to the level of potential risk and is established through a classification system based on that potential risk.

The classification risk is determined from:

- the manufacturer's intended purpose for the medical device, and
- a set of classification rules. These rules will classify medical devices into one of five classes of medical devices.

THE CLASSES OF MEDICAL DEVICES

The five classes of medical device based upon the classification rules are:

- Class I - for low risk medical devices
- includes low risk devices that are sterile and /or have a measuring function
- Class IIa - for low-medium risk medical devices,
- Class IIb - for medium–high risk medical devices,
- Class III - for high risk medical devices, and
- AIMD - for Active Implantable Medical Devices (are treated as Class III medical devices).

THE CLASSIFICATION RULES

Schedule 2 of the MD Regulations describes the classification rules that apply to:

- Non-invasive medical devices (Rule 2):
 - General (Rule 2.1),
 - Device to channel or store blood (Rule 2.2),
 - Device to modify biological or chemical composition of blood (Rule 2.3), and
 - Device to contact with injured skin (Rule 2.4).
- Invasive medical devices (Rule 3):
 - Device used to penetrate body orifices (Rule 3.1),
 - Surgically invasive device for transient use (Rule 3.2),
 - Surgically invasive device for short-term use (Rule 3.3), and
 - Surgically invasive device for long-term use and implantable devices (Rule 3.4).
- Active medical devices (Rule 4):
 - General (Rule 4.1),
 - Active device for therapy (Rule 4.2),
 - Active device for diagnosis (Rule 4.3), and
 - Active devices to administer or remove medicines from a patient's body (Rule 4.4).
- Special rules for medical devices:
 - Device incorporating a medicine (Rule 5.1),
 - Device for contraception or prevention of sexually transmitted disease (Rule 5.2),
 - Device for disinfecting, cleaning another medical device (Rule 5.3),
 - Non-active device to record X-ray diagnostic images (Rule 5.4),
 - Device containing animal tissues, cells or other substances, that will need to be rendered non-viable to mitigate any infectivity risk or microbial or recombinant tissues, cells or other substances (Rule 5.5),
 - Device that is a blood bag (Rule 5.6),
 - Active implantable device (Rule 5.7),
 - Device for export only (Rule 5.8), and
 - Device that is a mammary implant (Rule 5.9).

CLASSIFYING A MEDICAL DEVICE

DECIDING WHAT CLASSIFICATION RULES APPLY

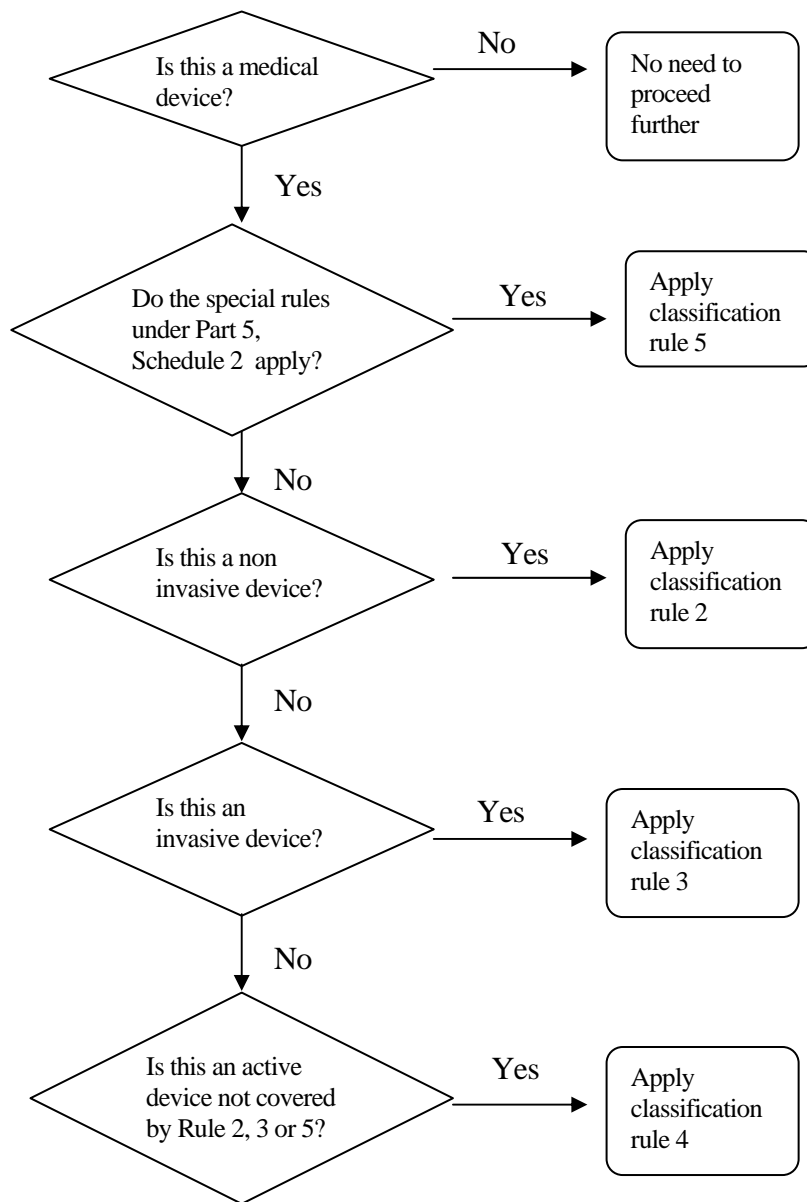
The following decisions need to be made before applying the classification rules:

- Is the product a medical device? Check the definition of a medical device on page 27,
- Do the special classification rules (Schedule 2, Part 5 of the MD Regulations) apply? See Flowchart 5- Special rules on page 21,
- Is the device intended to be non-invasive? See Flowchart 2 on page 10, (NB- If the device is sterile or has a measuring function conformity evidence will be needed),
- Is the device intended to be invasive through a body orifice? See Flowchart 3 on page 13,
- Is the device intended to be surgically invasive? See Flowchart 3A on page 14, or
- Is the device an active medical device? See Flowchart 4 on page 18.

IMPORTANT POINTS TO REMEMBER

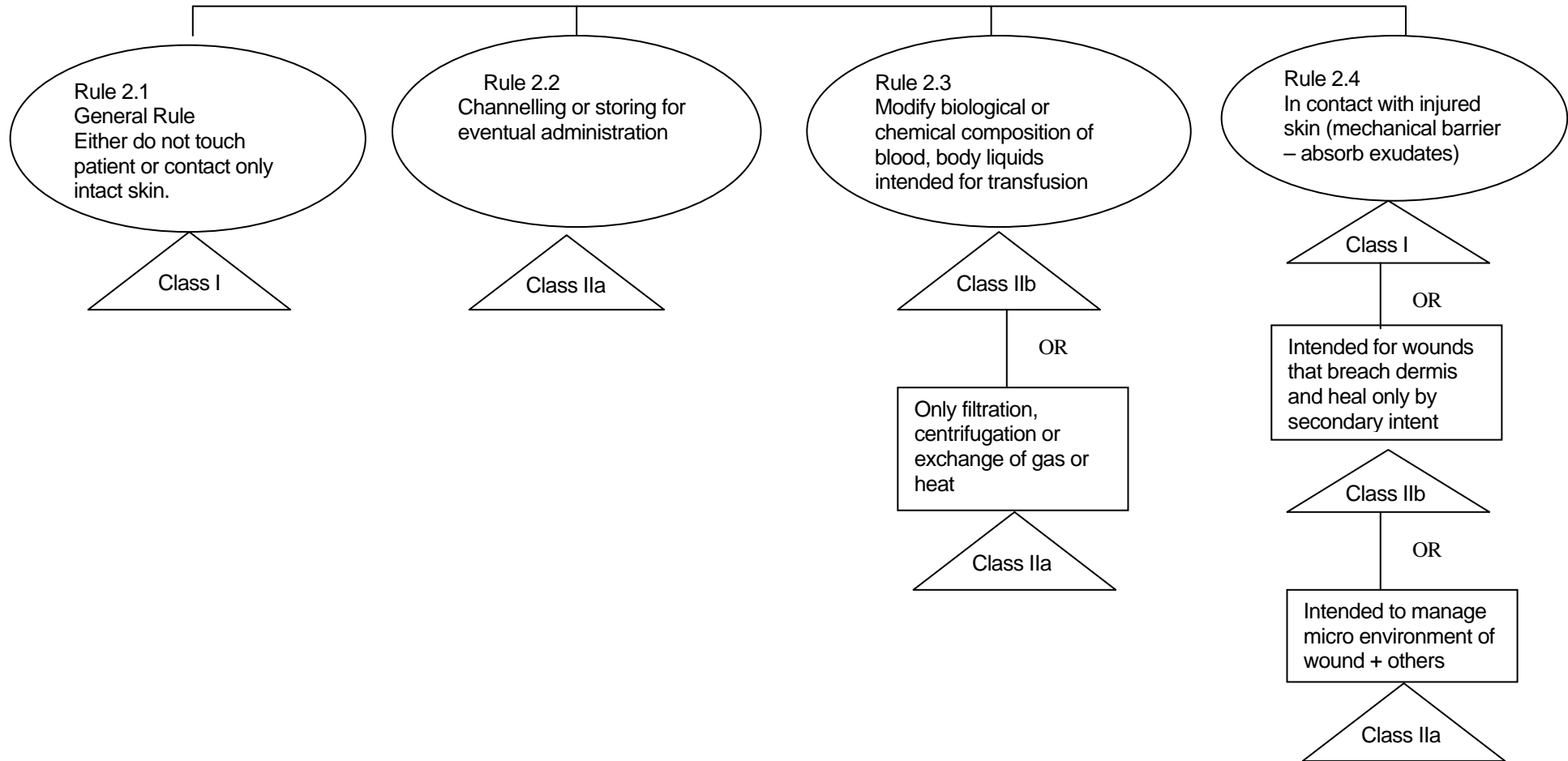
- The manufacturer is responsible for determining the class of a device.
- The classification rules are based on the manufacturer's intended purpose, taking into account the mechanism of action, and in some cases, more than one rule can apply. If this happens, the higher classification applies with the exception of medical devices for export only (Rule 5.8) which are classified as Class I.
- All the relevant classification rules must be considered to determine the class of the medical device.
- The classification must be consistent with the information accompanying the medical device including the label, directions for use, brochures and operating manuals.
- If the intended purpose is not clear in the information, the TGA will assume an intended purpose consistent with the purpose generally accepted in clinical practice.
- If the device is to be used in combination with another medical device, the classification rules must be applied separately to each device.
- Accessories are classified separate to the medical device they are used with.
- The duration for use must be specified for all invasive medical devices.
- If the device is not for use in a specific part of the body, its classification is based on the most critical specified use.
- Software intended to drive or influence the use of a medical device falls under the same classification as the medical device.
- Based on the intended purpose, software may be a medical device in its own right.

FLOWCHART 1- DECIDING WHAT CLASSIFICATION RULES APPLY



FLOWCHART 2 CLASSIFICATION RULES - NON INVASIVE DEVICES

These rules are described in Schedule 2, Part 2 of the Medical Devices Regulations



RULE 2 NON INVASIVE MEDICAL DEVICES

Rule 2.1 Non-invasive medical devices – general

This rule applies to all medical devices that are not covered by a specific rule, devices that contact intact skin and devices that do not touch the patient.

Rule 2.1	Examples
A non-invasive device is Class I, unless the device is classified at a higher level under another rule in Schedule 2 of the MD Regulations.	<p>Devices used to collect body liquid where a return flow is unlikely eg urine collection bottles, ostomy pouches, wound drainage collection bottles and incontinence pads.</p> <p>Devices used to immobilise body parts and/or to apply force or compression eg non-sterile dressings, plaster bandages, cervical collars and gravity traction devices or compression hosiery.</p>

Rule 2. 2 Non-invasive devices intended to channel or store blood, etc

Devices covered under this rule may be indirectly invasive. Typically, they channel or store substances that will be eventually delivered into the body.

Rule 2.2	Examples
A non-invasive device used to channel or store blood or body liquids that are to be infused, administered or introduced into a patient. Class IIa	Devices intended to be used to channel active drug delivery systems. Eg intravenous tubing, gastrostomy tubing, anaesthesia breathing circuits and pressure indicator and syringes for infusion pumps.
A non-invasive device to store an organ, parts of an organ or body tissue that is to be later introduced into a patient. Class IIa	<p>Devices to channel blood. Eg blood transfusion sets.</p> <p>Devices to temporarily store and transport of organs for transplant or for long term storage of biological substances and tissues such as corneas, sperm and human embryos.</p>
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. Class IIa.	Oxygen tubing & masks, anaesthetic tubing & breathing circuits and syringes & tubing for infusion pumps.

Rule 2.3 Non-invasive devices intended to modify the biological or chemical composition of blood, etc

Devices in this category must be considered separately from those in Rule 2.1, as they are indirectly invasive. The devices treat or modify substances that will be delivered into the body.

Rule 2.3	Examples
A non-invasive device to modify the biological or chemical composition of blood, other body liquids, or other liquids to be infused in the patient. Class IIb.	Devices intended to remove undesirable substances out of the blood by exchange of solutes such as hemodialyzers. Auto transfusion systems. Devices used to separate cells such as gradient medium for sperm.
A non-invasive device to be used in treatment consisting of filtration, centrifugation or exchanges of gas or heat. Class IIa.	Particulate filtration of blood in an extracorporeal circulation system, centrifugation of blood for transfusion or autotransfusion, removal of carbon dioxide from the blood and/or adding oxygen, and warming or cooling blood in the extracorporeal circulatory system.

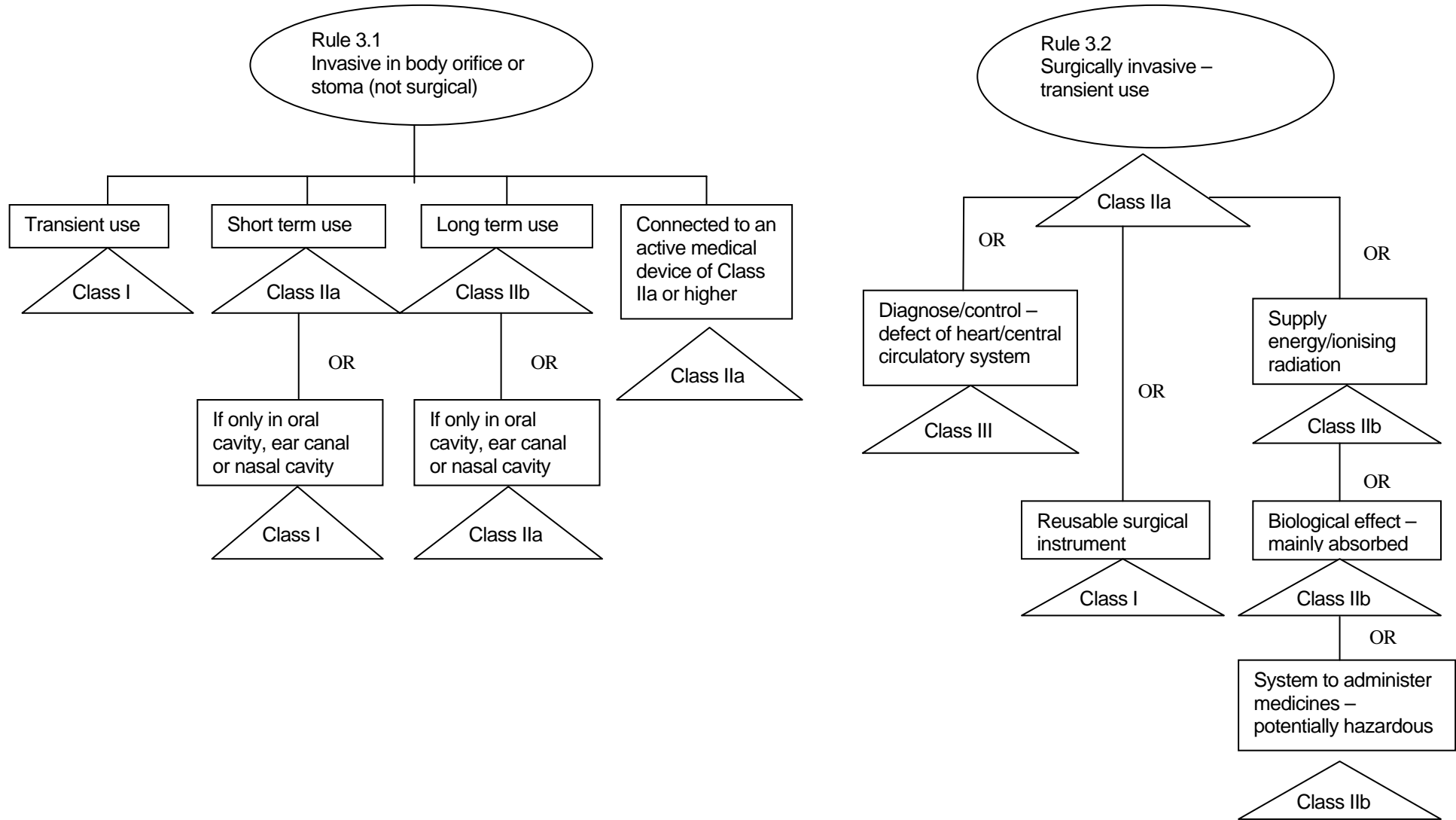
Rule 2.4 Non-invasive devices intended to have contact with injured skin

This rule covers wound dressings without consideration of the wound depth. The technology associated with these devices is well understood and they do not result in any great hazard to the patient.

Rule 2.4	Examples
A non-invasive device to be used in contact with injured skin (including a device the principal intention of which is to manage the microenvironment of a wound). Class IIa	Assists 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. Eg adhesives for topical use, polymer film dressings, hydrogel dressings and non-medicated impregnated gauze dressings.
A non-invasive device to be used as a mechanical barrier or for compression; or for absorption of exudates. Class I.	Absorbent pads, island dressings, cotton wool, wound strips and gauze dressings to act as a barrier or absorb exudates from the wound. (NB If the device is sterile conformity evidence is required)
A non-invasive device to be used for wounds that have breached the dermis and the wounds can only heal by secondary intent. Class IIb.	Intended for severe wounds that have extensively breached the dermis, and healing is by secondary intent (by granulation from the base of the wound). Eg dressings for chronic extensive ulcerated wounds, severe burn, severe decubitus wounds, or dressings providing a temporary skin substitute.

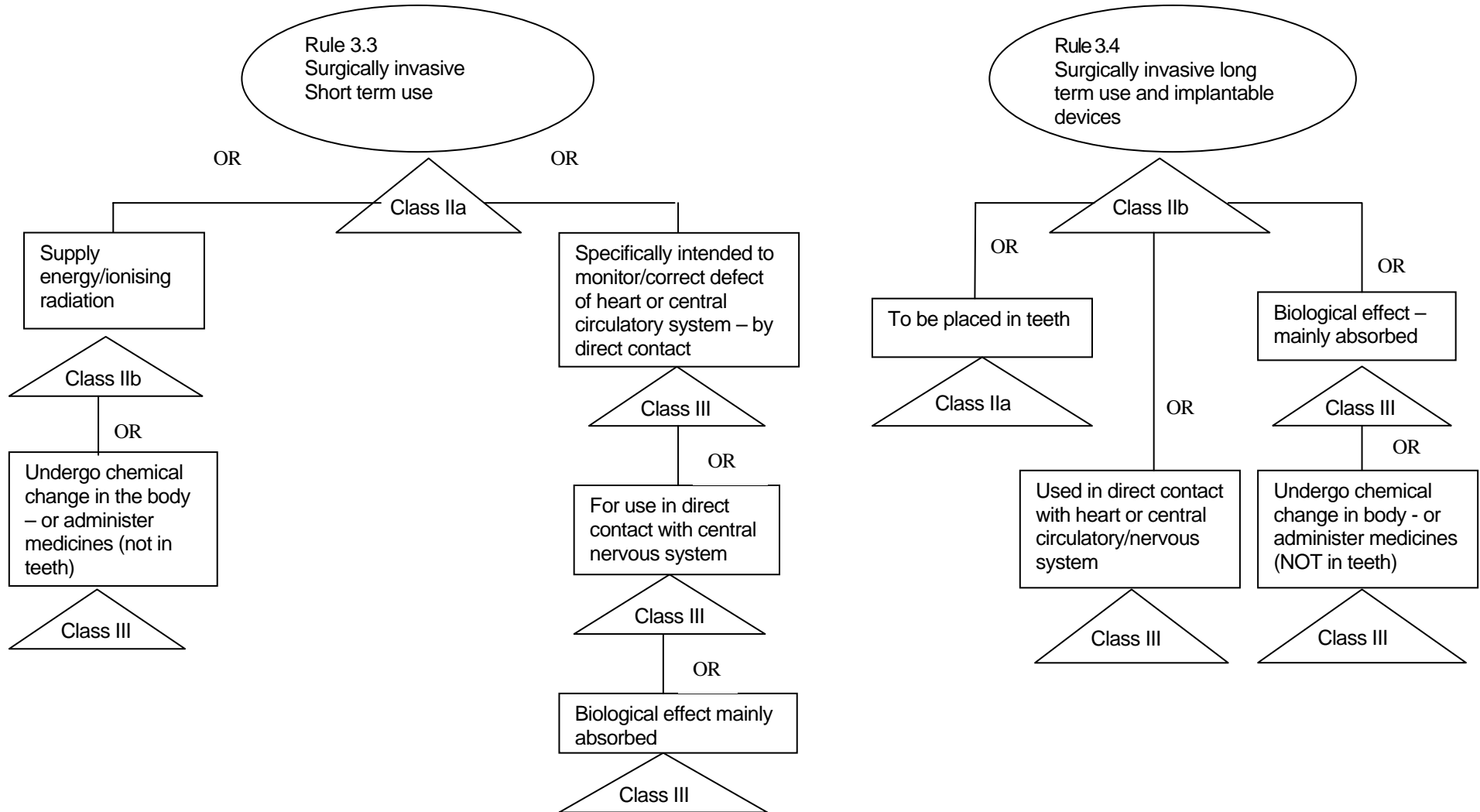
FLOWCHART 3 CLASSIFICATION RULES - INVASIVE DEVICES

These rules are described in Schedule 2, Part 3 of the Medical Devices Regulations



FLOWCHART 3A CLASSIFICATION RULES - INVASIVE DEVICES

These rules are described in Schedule 2, Part 3 of the Medical Devices Regulations



RULE 3 INVASIVE MEDICAL DEVICES

Rule 3.1 Invasive devices intended to be used to penetrate body orifices

This rule covers devices that enter the body through existing body orifices (eg ear mouth, nose, eye etc) and surgically created stomas. Devices covered by this rule tend to be for diagnostic and therapeutic use in particular specialities (ENT, ophthalmology, dentistry, proctology, urology and gynaecology).

Rule 3.1	Examples
<p>Invasive devices that are:</p> <ul style="list-style-type: none"> - not connected to an active medical device, and are for transient use. Class I; - for short-term use. Class IIa; - for use in the oral cavity as far as the pharynx, in an ear canal to the ear drum, or in a nasal cavity. Class I; and - for long-term use. Class IIb. <p>Invasive devices for use in the oral cavity as far as the pharynx or in an ear canal to the ear drum, or in a nasal cavity and is not liable to be absorbed by the mucous membrane. Class IIa.</p>	<p>Handheld dental mirrors, dental impression materials, exam gloves and prostatic balloon dilation catheters.</p> <p>Contact lenses, urinary catheters, tracheal tubes, stents, vaginal pessaries and perineal reduction devices.</p> <p>Dressing for nose bleeds, dentures removable by the patient.</p> <p>Long term urinary catheters, artificial eye and urethral stents.</p> <p>Orthodontic wire, fixed dental prostheses, fissures sealants.</p>
<p>Invasive device to be connected to an active medical device that is classified as Class IIa or higher. Class IIa.</p>	<p>Tracheostomy tubes connected to a ventilator, powered nasal irrigators, nasopharyngeal airways, heat and moisture exchangers and suction catheters or tubes for stomach drainage.</p>

Rule 3.2 Surgically invasive devices intended for transient use

This rule covers devices that are used to create a conduit through the skin (needles, cannulae, etc), surgical instruments (scalpels, saws, etc.) and various types of catheters, suckers, etc.

Rule 3.2	Examples
<p>Surgically invasive device for transient use. Class IIa.</p>	<p>Suture needles, hypodermic needles and syringes, suckers, surgical swabs and surgical gloves.</p>
<p>Surgically invasive device for transient use to diagnose, monitor, control or correct a defect of the heart, or central circulatory system through direct contact. Class III.</p>	<p>Cardiovascular catheters (eg. angioplasty balloon catheters), including related guidewires and coronary artery probes.</p>
<p>A reusable surgical instrument. Class I.</p>	<p>Scissors, artery forceps, tissue forceps, tissue clamps, excavators, osteotomes and chisels.</p>

<p>A surgically invasive device for transient use to supply ionising radiation.</p> <p>A surgically invasive device for transient use to have a biological effect.</p> <p>A surgically invasive device for transient use to be wholly, or mostly, absorbed by the body.</p> <p>A surgically invasive device for transient use to administer medicine via a delivery system, and the administration is potentially hazardous to the patient.</p> <p>Class IIb.</p>	<p>Catheters containing or incorporating radioactive radioisotopes where the isotope is not intended to be released into the body.</p> <p>Fibrin based tissue glues.</p> <p>Resorbable haemostat materials.</p> <p>Devices for repeated self-application where the dose and the medicine are critical, eg. personal insulin injectors (commonly referred to as pens).</p>
--	---

Rule 3.3 Surgically invasive devices intended for short-term use

This rule covers devices used in the context of surgery or post-operative care (eg clamps and drains), infusion devices (cannulae and needles) and catheters of various types.

Rule 3.3	Examples
<p>Surgically invasive device for short term use. Class IIa.</p>	<p>Clamps, infusion cannulae, skin closure devices or temporary filling materials, some surgical retractors eg chest retractors for cardiac surgery.</p>
<p>A surgically invasive device for short term use to supply ionising radiation, or</p> <p>A surgically invasive device for short term use device to undergo a chemical change in a patient's body (except a device intended to be placed in the teeth), or</p> <p>A surgically invasive device for short term use to administer medicine. Class IIb.</p>	<p>Bradytherapy devices.</p> <p>Biological tissue adhesives.</p> <p>An intravenous cannula.</p>
<p>A surgically invasive device 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;</p> <p>A surgically invasive device for short term use to be used in direct contact with the central nervous system; or</p> <p>A surgically invasive device for short term use to have biological effect; or be wholly, or mostly, absorbed by a patient's body.</p> <p>Class III</p>	<p>Cardiovascular catheters, cardiac output probes and temporary pacemaker leads. Thoracic catheters intended to drain the heart, including the pericardium and a carotid artery shunt.</p> <p>Neurological catheters, cortical electrodes and cononoid paddles.</p> <p>Absorbable sutures and bone anchors.</p>
<p>A surgically invasive device for short term use that is intended by the manufacturer to be placed in the teeth and to undergo a</p>	<p>Dental Adhesives used for root canal therapy.</p>

chemical change in the body is Class IIa . For this clause a medical device to be placed in the teeth includes a device that is intended to penetrate a tooth but does not enter the gum or bone beyond the tooth.	
--	--

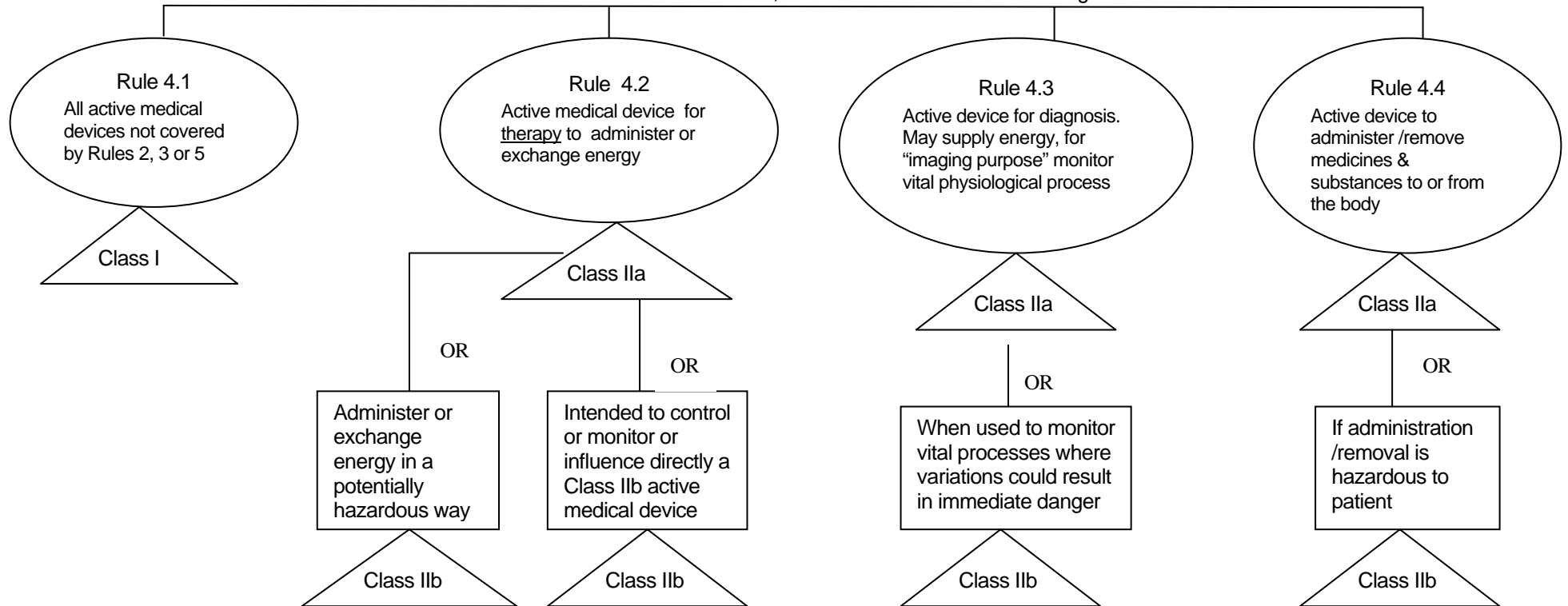
Rule 3.4 Surgically invasive devices for long-term use and implantable devices

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

Rule 3.4	Examples
A surgically invasive device for long-term use and implantable devices. Class IIb	Implantable joint replacements, shunts, stents, nails, plates and screws, intra-ocular lenses, infusion ports, peripheral vascular grafts, non-absorbable sutures, bone cements and maxillo-facial implants.
A surgically invasive device for long-term use to be placed in the teeth. Class IIa .	Bridges, crowns, dental filling materials and pins, dental alloys, ceramics and polymers.
A surgically invasive device for long-term use to be used in direct contact with the heart, the central circulatory system or the central nervous system.	Prosthetic heart valves, aneurysm clips, vascular prostheses, spinal stents, vascular stents, CNS electrodes and cardiovascular sutures.
A surgically invasive device for long-term use to have a biological effect.	Permanent vena cava filters.
A surgically invasive device for long-term use to be wholly, or mostly, absorbed by a patient's body.	Absorbable sutures, bioactive adhesives and implants through the attachment of surface coatings such as phosphorylcholine.
A surgically invasive device for long-term use to undergo a chemical change in the patient's body (except a device that is to be placed in the teeth); or	
A surgically invasive device for long-term use to administer medicine. Class III	Rechargeable non-active drug delivery systems.
A surgically invasive device for long-term use that is intended by the manufacturer to be placed in the teeth and to undergo a chemical change in -the body is Class IIa . For this clause a medical device to be placed in the teeth includes a device that is intended to penetrate a tooth but does not enter the gum or bone beyond the tooth.	

FLOWCHART 4 CLASSIFICATION RULES - ACTIVE DEVICES

These rules are described in Schedule 2, Part 4 of the Medical Devices Regulations



RULE 4 ACTIVE MEDICAL DEVICES

Rule 4.1 Active medical devices – general

This rule applies to active medical devices that are not covered by a specific rule.

Rule 4.1	Examples
An active device is Class I , unless the device is classified at a higher level under another rule in Schedule 2 of the MD Regulations.	Examination lights, surgical microscopes, diagnostic devices for thermography, active devices for recording, processing or viewing of diagnostic images and dental curing lights.

Rule 4.2 Active medical devices for therapy

This rule covers devices that are electrical equipment used in surgery, devices used in specialised treatments and stimulation devices.

Rule 4.2	Examples
An active device for therapy to administer energy to a patient, or exchange energy to or from a patient. Class IIa.	<p><u>Electrical, magnetic and electromagnetic energy</u>- muscle stimulators, external bone growth stimulators, TENS devices and electrical acupuncture.</p> <p><u>Thermal energy</u>- warming blankets except for unconscious patients, cryosurgery equipment and heat exchangers.</p> <p><u>Mechanical energy</u>- powered dermatomes, drills and dental hand pieces.</p> <p><u>Light</u>- phototherapy for skin treatment and for neonatal care</p> <p><u>Sound</u>- hearing aids.</p>
An active device to administer or exchange energy in a potentially hazardous way, having regard to the nature, density and site of application of the energy. Class IIb.	<p><u>Kinetic Energy</u>- lung ventilators.</p> <p><u>Thermal Energy</u>- infant incubators, warming blankets for unconscious patients, blood warmers, heat exchangers used in intensive care.</p> <p><u>Electrical Energy</u>- high frequency electrosurgical generators, electrocautery, external defibrillators, electroconvulsive therapy equipment.</p> <p><u>Coherent Light</u>- surgical lasers.</p> <p><u>Ultrasound</u>- lithotriptors, physiotherapy ultrasound devices.</p> <p><u>Ionising Radiation</u> - radioactive sources for after-loading therapy, therapeutic cyclotrons, linear accelerators, therapeutic X-ray sources.</p>
An active device to control or monitor, or directly influence the performance of an active medical device for therapy of the kind mentioned in the 2nd box above. Class IIb.	External feedback systems for active therapeutic devices, after-loading control devices.

Rule 4.3 Active medical devices for diagnosis

This rule covers devices that are used in ultrasound diagnosis and capture of physiological signals and devices used in therapeutic and diagnostic radiology.

Rule 4.3	Examples
<p>A device to supply energy that will be absorbed by a patient's body (except a device that illuminates the patient's body in the visible spectrum).</p> <p>A device to be used to image in vivo distribution of radiopharmaceuticals in patients.</p> <p>Devices to allow direct diagnosis or monitoring of vital physiological processes of a patient (except a device mentioned in the 1st paragraph in the box below).</p> <p>Class IIa.</p>	<p>Magnetic resonance equipment, pulp testers, evoked response stimulators, diagnostic ultrasound.</p> <p>Gamma cameras, positron emission tomography and single photon emission computer tomography.</p> <p>Electrocardiographs, electroencephalographs, cardiscopes with or without pacing pulse indicators and electronic thermometers.</p>
<p>A device to monitor vital physiological parameters of a patient, and the nature of variations monitored could result in immediate danger to the patient.</p> <p>A device to emit ionising radiation and to be used for diagnostic or therapeutic interventional radiology, or</p> <p>A device to control, monitor, or directly influence the performance of a device in the previous paragraph. Class IIb</p>	<p>Intensive care monitoring systems, biological sensors, blood gas analysers used in open-heart surgery, cardiscopes and apnea monitors, including those in home care.</p> <p>Diagnostic X-ray sources.</p>

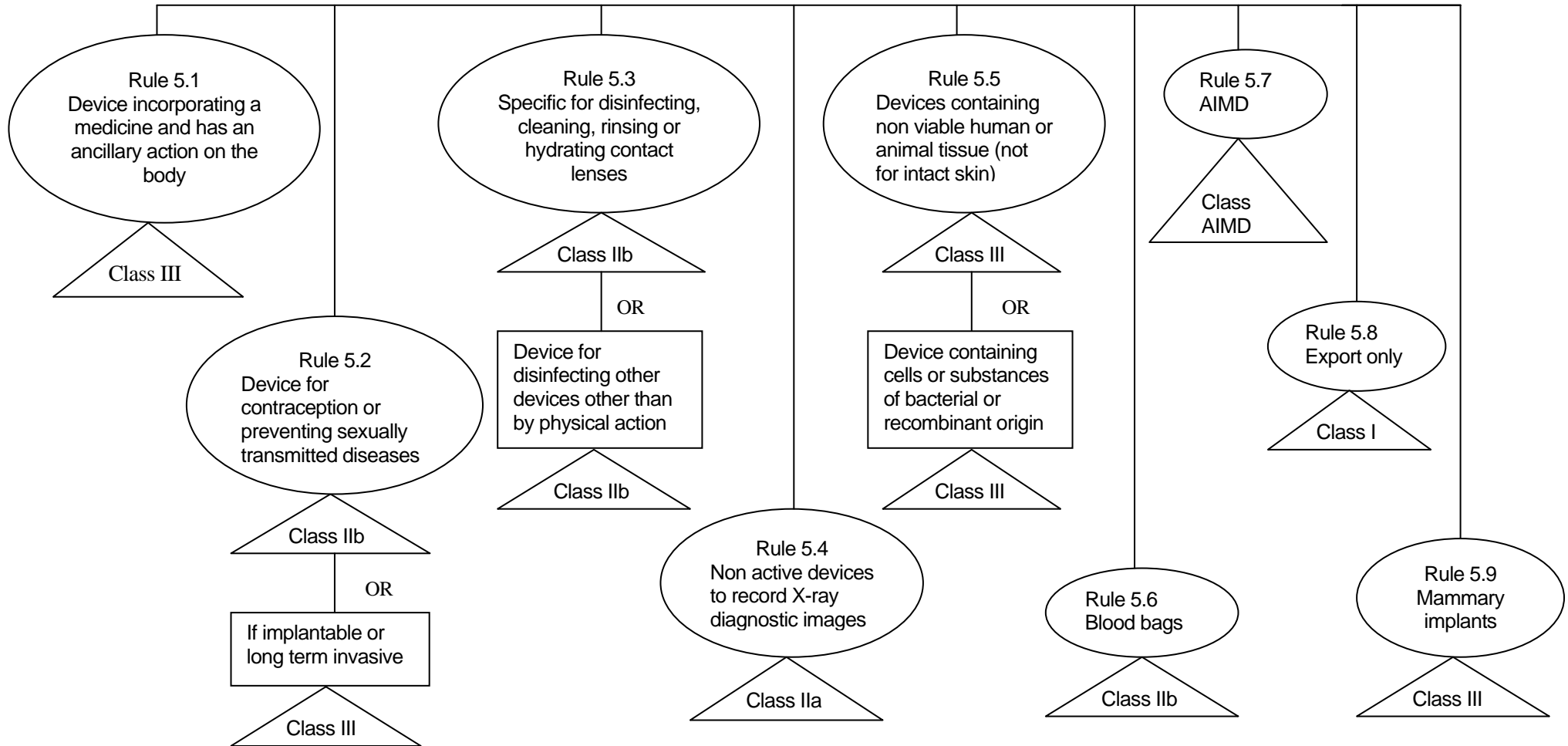
Rule 4.4 Active medical devices intended to administer or remove medicines, etc from a patient's body

This rule covers drug delivery systems and anaesthesia equipment.

Rule 4.4	Examples
<p>An active device to administer or remove medicine, body liquids or other substances. Class IIa</p>	<p>Suction equipment, feeding pumps Jet injectors for vaccination.</p>
<p>An active device to administer or remove medicine, body liquids or other substances in a way that is potentially hazardous to the patient, having regard to the substances, the part of the body concerned, and the characteristics of the device.</p> <p>Class IIb.</p>	<p>Infusion pumps, ventilators, anaesthesia machines, anaesthetic vaporisers, dialysis equipment, blood pumps for heart-lung machines, hyperbaric chambers, pressure regulators for medical gases, medical gas mixers, moisture exchangers in breathing circuits. Nebulisers where the failure to deliver the appropriate dosage form could be hazardous.</p>

FLOWCHART 5 CLASSIFICATION RULES –SPECIAL RULES

These rules are described in Schedule 2, Part 5 of the Medical Devices Regulations



RULE 5 SPECIAL RULES

Rule 5.1 Devices incorporating 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.

Clause 5.1	Examples
A device incorporating a substance that if used separately would be a medicine and has an ancillary action on the body. Class III	Antibiotic bone cements, 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.

Rule 5.2 Devices for contraception or prevention of sexually transmitted diseases

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

Rule 5.2	Examples
A device for contraception or the prevention of sexually transmitted diseases. Class IIb.	Condoms, contraceptive diaphragms.
An implantable or invasive device for long-term use. Class III.	Contraceptive intrauterine devices (IUDs) and surgically implanted contraceptive devices.

Rule 5.3 Devices intended for disinfecting, cleaning, rinsing etc

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

Rule 5.3	Examples
A device specifically for disinfecting, cleaning, rinsing or hydrating contact lenses. Class IIb	Contact lens solutions, comfort solutions.
A device specifically for disinfecting another medical device. Class IIb	Disinfectants for haemodialysis devices or endoscopes, sterilisers to sterilise medical devices and washer disinfectors.

Rule 5.4 Non-active devices intended to record X-ray diagnostic images

A non-active medical device to record X-ray diagnostic images such as X-ray films, photostimulable phosphor plates are **Class IIa.**

Rule 5.5 Devices containing non-viable animal tissues or derivatives

This rule covers devices that contain or are made of animal tissues that have been rendered non-viable or derivatives from such tissues also being non-viable. Rendering non-viable refers primarily to the inactivation of any infective agent that has been identified in a risk analysis as being potentially transmissible.

Rule 5.5	Examples
Devices containing animal tissues or derivatives that have been rendered non-viable and not intended to come into contact with intact skin only. Class III.	Biological heart valves, porcine xenograft dressings, catgut sutures, implants and dressings made from collagen.
A devices that contains tissues, cells or substances of bacterial or recombinant origin or a combination of tissues, cells or substances of animal, bacterial or recombinant origin. Wherever these devices contain material of bacterial or recombinant origin, they are Class III , even if they only come into contact with intact skin.	Intra-ocular fluids, meniscus joint fluid replacement, anti-adhesion barriers, tissue fillers based on hyaluronic acid derived from bacterial fermentation processes.

Rule 5.6 Devices that are blood bags

Rule 5.6	Examples
A device that is a blood bag Class IIb. If the blood bags have a function greater than storing purposes and include systems for preservation other than anti-coagulants then other rules (eg. rule 5.1) may apply.	Blood bags (including those containing or coated with an anticoagulant).

Rule 5.7 Active implantable medical devices

An active implantable medical device is classified as Class AIMD.

Rule 5.7	Examples
An implantable accessory to an active implantable device.	Electrode leads associated with pacemakers, defibrillators and nerve stimulators.
An active device to control, monitor, or directly influence the performance of an active implantable device. Class III	Clinician's programming device for pacemakers, patient control device for nerve stimulation devices.

Rule 5.8 Medical devices for export only

A device that is intended by the manufacturer for export only is classified as **Class I.**

Rule 5.9 Devices that are mammary implants

A device that is a mammary implant is classified as **Class III.**

APPENDIX A - DEFINITIONS

Accessory (reference subsection 3(1) of the Act)

An article that its manufacturer specifically intended to be used together with a medical device to enable the device to be used as the manufacturer of the device intended.

Active implantable medical device (reference- Dictionary in the MD Regulations)

An active medical device (other than an implantable medical device) that is intended by the manufacturer:

(a) either:

(i) to be, by surgical or medical intervention, introduced wholly, or partially, into the body of a human being, or

(ii) to be, by medical intervention, introduced into a natural orifice in the body of a human being, and

(b) to remain in place after the procedure.

Examples: Pacemaker, nerve stimulator, artificial cochlear and implantable bradytherapy seeds.

Active medical device (reference- Dictionary in the MD Regulations)

A medical device that is intended by the manufacturer:

(a) To depend for its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity), and

(b) To act by converting this energy; but

does not include a medical device that is intended by the manufacturer to transmit energy, a substance, or any other element, between an active medical device and a human being without any significant change in the energy, substance, or other element being transmitted.

Examples: surgical diathermy, surgical lasers, air driven surgical drills and saws, powered traction systems and examination lights.

Active medical device for diagnosis (reference- Dictionary in the MD Regulations)

An active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to supply information for the purpose of detecting, diagnosing monitoring or treating physiological conditions, states or health, illness or congenital deformities.

Example: Ultra sound device

Active medical device for therapy (reference- Dictionary in the MD Regulations)

An active medical device that is intended by the manufacturer to be used on a human being, either alone or in combination with another medical device, to support, modify, replace or restore biological functions or structures for the purpose of treating or alleviating an illness, injury or handicap.

Examples: therapeutic laser, infant incubator, lung ventilator, deep heat therapy lamp and an electrical muscle stimulator.

Ancillary action (reference – European Commissions Guidelines relating to Medical Device Directives – *MEDDEV 2.4/1 – rev 8 Part 2: Guidelines for the Classification of Medical Devices - July 2001* (MEDDEV 2.4/1))

The action of the medicine is subordinate/subsidiary to that of the device.

Biological effect (reference – MEDDEV 2.4/1)

A material is considered to have a biological effect if it actively and intentionally induces, alters or prevents a response from the tissues that is mediated by specific reactions at a molecular level. Such a device may be described as bioactive.

Body orifice (reference- Dictionary in the MD Regulations)

A natural opening or a permanent artificial opening, in a human being's body, and includes the external surface of the eyeball.

Examples: Includes stomas such as a colostomy, gastrostomy and tracheostomy.

Central circulatory system (reference- Dictionary in the MD Regulations)

The system in a human being comprising the following vessels:

- Arteriae pulmonales (pulmonary artery)
- Aorta ascendens (ascending aorta)
- Arteriae coronariae (coronary artery)
- Arteria carotis communis (common carotid artery)
- Arteria carotis externa (external carotid artery)
- Arteria carotis interna (internal carotid artery)
- Arteria cerebrates (cerebella arteries)
- Truncus brachicephalicits (brachiocephalic trunk)
- Venae cordis (cardiac veins)
- Venae pulmonales (pulmonary vein)
- Vena cava superior (superior vena cava)
- Vena cava inferior (inferior vena cava)
- Arcus aorta (aortic arch)
- Thoracica aorta (thoracic aorta)
- Abdominalis aorta (abdominal aorta)
- Iliaca communis (common iliac arteries and veins).

Note: The thoracic aorta, abdominal aorta and the common iliac are not considered part of the definition of the central circulatory system in the EU Medical Devices Directive - this will result in differences between Australia and the EU in classifying devices used for these vessels.

Central nervous system (reference- Dictionary in the MD Regulations)

The system in a human being comprising the brain, meninges and spinal cord.

Chemical change (reference – MEDDEV 2.4/1)

Chemical change does not apply to products such as bone cements where the chemical change takes place during the placement and does not continue in long term.

Direct diagnosis (reference – MEDDEV 2.4/1)

Continuous surveillance by direct measurement.

Duration (reference Classification Rules Part 1 (1.1) Schedule 2 of the MD Regulations)

Transient - intended to be used continuously for less than 60 minutes.

Short term - intended to be used continuously for at least 60 minutes but not more than 30 days.

Long term - intended for continuous use for more than 30 days.

Implantable medical device (reference- Dictionary in the MD Regulations)

A medical device (other than an active implantable medical device) that is intended by the manufacturer:

(a) to be, by surgical intervention, wholly introduced into the body of a human being, and to remain in place after the procedure, or

(b) to replace, by surgical intervention, an epithelial surface, or the surface of an eye, of a human being, and to remain in place after the procedure, or

(c) to be, by surgical intervention, partially introduced into the body of a human being, and to remain in place for at least 30 days after the procedure.

Examples: cardiovascular stent, bone plates and screws, intra-ocular lenses, internal/external fixation systems, resorbable anti-adhesion barriers and heart valve prosthesis.

Integral (reference – MEDDEV 2.4/1)

A device and the ancillary medicine form a single physical unit.

Intended purpose (reference- Dictionary in the MD Regulations)

The purpose for which the manufacturer of the device intends it to be used, as stated in:

(a) the information provided with the device, or

(b) the instructions for use of the device, or

(c) any advertising material applying to the device, and

(d) the mechanism of action of the device.

Note: The mode of action of a device must be consistent with the intended purpose of the device. Where not stated explicitly it will be assumed that the device will be used in accordance with reasonably foreseeable Australian medical practice.

Invasive medical device (reference- Dictionary in the MD Regulations)

A medical device that is intended by the manufacturer to be used, in whole or in part to penetrate the body of a human being through a body orifice or through the surface of the body.

Examples: wound drains, colonoscope, gastroscope, artificial larynx, urinary catheter, hypodermic needle, naso-gastric tube, and a feeding tube.

Measuring function (reference- Regulation 1.4 of the MD Regulations)

A measuring function is one intended by the manufacturer to measure quantitatively, a physiological or anatomical parameter, or a quantity, or a qualifiable characteristic, of energy or substances delivered to or removed from the body. Is displayed in Australian units of measurement or other units of measurement approved by the Secretary, of the particular device, or

is compared to at least one point of reference indicated in such units, and must be accurate to enable the device to achieve its intended purpose.

Medical device (reference- Section 41BD of the Act)

A medical device is:

- (a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
 - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
 - (iii) investigation, replacement or modification of the anatomy or of a physiological process;
 - (iv) control of conception;and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or
- (c) an accessory to such an instrument, apparatus, appliance, material or other article.

Potentially hazardous (reference – MEDDEV 2.4/1)

The concept of “potentially hazardous” is dependent on the type of technology involved and the intended application of the device to the patient and not on the measures adopted by the manufacturer in view of good design management. A device is potentially hazardous if the basic risk of the device before deliberate measures have been taken to minimise risk by inherent design or protection mechanisms, is considered intolerable. For example all devices intended to emit ionizing radiation, all lung ventilators and lithotriptors should be in a higher risk class.

Reusable surgical instrument (reference- Dictionary in the MD Regulations)

A medical device that is intended by the manufacturer:

- (a) to be used surgically, without being connected to an active medical device, for cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or any other similar procedure, and
- (b) to be used after the appropriate procedures specified by the manufacturer in the instructions for use have been carried out.

Surgically invasive medical device (reference- Dictionary in the MD Regulations)

- (a) An invasive medical device that is intended by the manufacturer to be used with the aid, or in the context of, a surgical operation, and
- (b) A medical device that is intended by the manufacturer to be used to penetrate the body of a human being in any way other than through a body orifice.

Examples: scalpel blades, biopsy devices, surgical instruments, skin stapling devices, staples, clips and clamps for blood vessels tissues or organs, coronary angioplasty balloon catheters.

Vital physiological process (reference – MEDDEV 2.4/1)

Includes respiration, heart rate, cerebral functions, blood gases, blood pressure and body temperature. Medical devices intended to be used for continuous surveillance of vital physiological processes in anaesthesia, intensive care or emergency care are in a higher risk class, whilst medical devices intended to be used to obtain readings of vital physiological signals in routine check ups and in self-monitoring are in a lower risk class.

Wholly or mainly absorbed

Refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.