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# **CANADIAN RULE BASED CLASSIFICATION SYSTEM (non-IVDD)**

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**Life Sciences British Columbia  
NRC-Industry Research Assistance Program**

**Health Canada Regulations on Medical Devices**

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Nancy Shadeed  
A/Manager, Device Licensing Division  
Medical Devices Bureau (MDB)  
Therapeutic Products Directorate (TPD)



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# CLASSIFICATION OF A MEDICAL DEVICE

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The degree of regulatory oversight assigned to a medical device is dependent upon its classification

# SCHEDULE 1 – THE CLASSIFICATION RULES

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- To determine the classification of a device, you must apply all of the rules in Schedule 1
  - Part 1 applies to devices in general
  - Part 2 applies to in Vitro Diagnostic Devices
- You must consider the labelled indications for use, or claims made for your device

# THE UNDERPINNING LOGIC THOUGHT TO THE SYSTEM

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- IVDD's – cogent, encompassing
  - Based on public health and individual risk and IVDD use outcome
- NON-IVDD's – more diverse
  - Large number of variables
  - Rapid technological advances
  - Classification criteria based on
    - The human body
    - Inherent device related potential hazards
    - Customary device use (O.R., I.C.U., N.I.C.U.)

# INVASIVE DEVICES

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- **“Invasive device”** means a medical device that is intended to come into contact with the surface of the eye or penetrate the body, either through a body orifice or through the body surface
- **“Surgically invasive device”** means an invasive device that is intended to enter the body through an artificially created opening that provides access to body structures and fluids

# INVASIVE DEVICES

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- **“Central cardiovascular system”** means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachiocephalic artery, aorta, inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries
- **“Surgical or dental instrument”** means a reusable medical device that is intended for surgical or dental use, including cutting, drilling, sawing, scraping, clamping, hammering, puncturing, dilating, retracting or clipping, without connection to an active device

# INVASIVE DEVICE – RULES 1 TO 3

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## Rule 1 – All surgically invasive devices are:

**Class II** (Surgical Needle, Urethral Catheter, Bronchial Cannula), **EXCEPT:**

- Those intended to diagnose, monitor, control or correct defect of CVS or CNS or fetus in utero – **Class IV** (Pacemaker, Spinal Cord Stimulator, Fetal Blood Sampling Endoscope)
- Those absorbed or intended to remain in the body for more than 30 days – **Class III** (Hip Prosthesis, Dental Cement, Absorbable Staple)



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# INVASIVE DEVICES – RULE 1 TO 3

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## Rule 2 – All invasive devices are:

**Class II** (Contact Lens, Laproscope, ENT Syringe)

### EXCEPT:

- Placed in oral or nasal cavities up to the pharynx, or the ear up to the ear drum – **Class I** (Ear Cannula, Nasal Aspirator, Orthodontic Mouth Guard)
- If intended to remain in the body for more than 30 days – **Class III** (Permanent Urethral Stent, Internal Nose Prosthesis, IUD)
- Intended to prevent or reduce the transmission of STD's – **Class III** (Intravaginal Pouch, Non-Latex Condom)

# INVASIVE DEVICES – RULES 1 TO 3

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## Rule 3 details the exceptions to Rules 1 and 2:

- All denture materials and orthodontic appliances and their accessories – **Class II** (Dental Foil, Artificial Teeth, Orthodontic Bracket)
- All surgical or dental instruments as defined in Regulations – **Class I** (Re-usable Surgical Knife)

- All latex condoms – **Class II**



# NON-INVASIVE DEVICES – RULES 4 TO 7

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## Rule 4 – Barrier Devices:

- All non-invasive devices which come into contact with injured skin – **Class II** (Wound and Burn Dressing – hydrogel, Medicated Pad)
- Except if device is intended only as a mechanical barrier, compression or absorption – **Class I** (Bandage Gauze, Adhesive Strip, Liquid Bandage)



# NON-INVASIVE DEVICES – RULES 4 TO 7

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## Rule 5 – Containment Devices:

- A non-invasive device intended for storing or channelling substances for administration – **Class II** (I.V. Administration Set, Ventilator Tubing, Irrigating Syringe)



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# NON-INVASIVE DEVICES – RULES 4 TO 7

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## Rule 6:

- A non-invasive device intended to modify the biological or chemical composition of body fluids, for the purpose of administration – **Class III** (Parallel Flow Dialyser, Hemoperfusion Apparatus)
- If the process may introduce a potentially hazardous foreign substance to the body – **Class IV** (Ex Vivo Photodynamic Cell Processor, Stem Cell Separator)
- If the process is accomplished by centrifugation, gravity filtration or the exchange of gas or heat – **Class II** (Infusion Line Filter)

# NON-INVASIVE DEVICES – RULES 4 TO 7

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## Rule 7 – All others:

- All other non-invasive devices – **Class I**  
(Mechanical Stethoscope)

### **EXCEPT:**

- If it is intended to be attached to an active device or to act as a calibrator, tester or quality control support to another medical device – **Class II**  
(Gas Flow Calibrator, Pacemaker Electrode Function Tester, Radiology Quality Assurance Tester)



# ACTIVE DEVICES

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- **“Active Diagnostic Device”** means an active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity
- **“Active Therapeutic Device”** means an active device that, whether used alone or in combination with another medical device, is intended to support, modify, replace or restore a biological function or structure for the purpose of treating or mitigating and illness or injury or a symptom of an illness or injury

# ACTIVE DEVICES

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- **“Active Device”** means a medical device that depend for its operation on a source of energy other than energy generated by the human body or gravity. A medical device that transmits or withdraws energy or a substance to or from a patient without substantially altering the energy or the substance is not an active device

# ACTIVE DEVICES – RULES 8 TO 12

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## Rule 8 – Ionizing Radiation

- Active device emitting ionizing radiation, including software and accessories – **Class III** (Bone Densitometer, I-125 Isotope Seed)
- Except, if the device is used in radiographic mode – **Class II** (Filmless X-Ray Imaging System)
- Except, an active device intended to be used for mammographies – **Class II** (Mammographic X-Ray System)

# ACTIVE DEVICES – RULES 8 TO 12

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## Rule 9 – Active Therapeutic Devices:

- Active therapeutic devices intended to administer or withdraw energy – **Class II** (Powered Traction, Powered Bone Drill, Dermatological Ultraviolet Lamp)
- If this results in a potentially hazardous situation – **Class III** (External Defibrillator, Electrosurgical Cutting/Coagulation Device)
- If the device is controlled by a closed-loop system – **Class IV** (External Defibrillator with Sensing/Pacing Function)

# ACTIVE DEVICES – RULES 8 TO 12

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## Rule 10 – Active Diagnostic Devices

- Active diagnostic devices that supply energy for imaging or monitoring physiological processes – **Class II** (Long Term ECG Recorder)
- If an erroneous reading could result in immediate danger – **Class III** (Pulse Rate Monitor, Physiological ECG Telemetry Unit, Dialysis Temperature Monitor)

# ACTIVE DEVICES – RULES 8 TO 12

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## Rule 11 – Active Devices

- Active devices intended to administer or withdraw substances from the body – **Class II** (Portable Aspiration Pump, Powered Nebulizer Pump, Suction Irrigator)
- If the administration or withdrawal is potentially hazardous – **Class III** (Ambulatory Infusion Pump, Anesthesia Ventilator Unit)
- If the device is controlled by a closed-loop system – **Class IV** (Closed Loop Blood Glucose Controller, Closed Loop Blood Pressure Controller)



# ACTIVE DEVICES – RULES 8 TO 12

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## Rule 12 – Other Active Devices

- Any other active device – **Class I**  
(Fiberoptic Surgical Light, Surgical Camera,  
Physiological Signal Amplifier)



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# SPECIAL RULES – RULES 13 TO 16

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These rules alter the normal classification of devices depending upon specific perceived risks and hazards

## **Rule 13 – Transfusion and Transplantation Safety:**

Devices intended to disinfect or sterilize blood, tissues or organs for transfusion or transplant...Class IV

(Blood Irradiator to prevent Graft vs. Host Disease)

All other devices intended to disinfect or sterilize a medical devices are...Class II

(Powered Soft Lens Thermal Sterilizer, Dialyzer Reprocessing Unit, Steam Sterilizer)

# SPECIAL RULES – RULES 13 TO 16

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## **Rule 14 – Biological Safety Issues:**

Devices manufactured from or incorporating animal or human tissue, or produced through recombinant technology...Class IV

(Collagen Corneal Shield, Bone Graft, Collagen Dermal Implant)

Except devices intended only to come in contact with intact skin...Class 1

(Leather Straps)



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# SPECIAL RULES – RULES 13 TO 16

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## Rule 15 – Custom Use:

Materials sold to health care professionals or dispensers intended to be fabricated into a medical device to meet the needs of an individual is classified the same as the final product

(Silicone Blocks to be used in reconstructive surgery)



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# SPECIAL RULES – RULES 13 TO 16

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## Rule 16 – Table:

- The classification of any medical device may be changed by adding it to the Table to this rule
- This would require public consultation and a regulatory amendment
  - Breast implants (Class IV)
  - Tissue expanders for breast reconstruction

and augmentation (Class IV)



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