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GUIDANCE DOCUMENT

Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs)

Published by authority of the
Minister of Health

Date Adopted	2015/04/23
Effective Date	2015/06/12

Health Products and Food Branch

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Également disponible en français sous le titre : Ligne directrice : Orientation sur le système de classification fondé sur le risque des instruments autres que les instruments diagnostiques in vitro (IDIV)

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document **may be** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

Document Change Log			
File name	Guidance on the Risk-based Classification System	Replaces	Draft Guidance for the Risk-based Classification System
Date	2015/06/12	Date	1998/05/04

Change	Location (section, paragraph)	Nature of and/or Reason for Change
1	Full document	Rewritten to add clarity; conform to Good Guidance Practices; and update examples.

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1.0 INTRODUCTION

The *Medical Devices Regulations* (Regulations) utilize a risk-based approach to regulating products within its scope. The safety and effectiveness evidence required to support a medical device licence application is proportional to the risk of the device, which is determined by applying the Classification Rules for Medical Devices detailed in Schedule 1 of the Regulations. As per section 6 of the Regulations, medical devices are classified into one of four classes where Class I represents the lowest risk and Class IV the highest.

1.1 Policy Objective

This guidance document is intended to clarify the application of the risk classification rules set out in the Regulations for non-*in vitro* diagnostic devices.

The risk classification scheme was developed to categorize medical devices according to the hazard a particular device presents and not the probability that harm will occur.

1.2 Policy Statements

The rules developed for the Canadian classification system borrow significantly from those which appear in the European Union's Council Directive 93/42/EEC. Many of the rules and interpretations of terms are either the same as, or similar to, those proposed by the European Union in the supporting documentation to the Council Directive. It does not necessarily hold true, however, that a medical device classified in one class according to the European Union's classification system will be classified in the same class based on the Canadian classification system. Manufacturers must apply the rules set out in Schedule 1 of the Regulations to determine the appropriate classification for their device in Canada.

The following indicators of risk posed by a given device were used to create the Canadian classification rules: degree of invasiveness, duration of contact, body system affected, and local versus systemic effects.

The risk classification system takes into consideration the duration of use of a medical device. The use of a medical device is either long term or not. Long term use implies continuous use for a period of 30 or more days. Continuous use is understood to be uninterrupted use for the intended purpose.

It is the intended use of the device that primarily determines the class of the device. Classification must be consistent with the claims that appear on the label of the device, including brochures, operating manuals, and the directions for use. If the intended use is not specified on the label of the device, then the intended use will be deemed to be that accepted in general medical practice.

The manufacturer must take into consideration all of the rules in order to establish the proper classification for their device. A device may fall under more than one rule. For example, a general rule (invasive/non-invasive) that is not specific to active devices may, nonetheless, apply to an active device. The final classification of the device, however, will be determined by the rule which assigns the higher risk.

It is acknowledged that any rule system has limitations and cannot accommodate all devices. There may be cases where either a device cannot be classified by the existing rules because of an unusual characteristic, or where the resulting classification does not reflect known hazards associated with the use of the device. In these cases, the device may be listed in the table accompanying Rule 16 of the Regulations.

In the event of a discrepancy between the manufacturer and Health Canada regarding the classification of a medical device, the final decision rests with Health Canada. The manufacturer, however, may request a reconsideration of this decision.

1.3 Scope and Application

This document applies only to the classification of non-*in vitro* diagnostic devices (non-IVDDs). Classification rules for IVDDs are discussed in the guidance document, “Guidance for the Risk Based Classification System of *In Vitro* Diagnostic Devices”.

The classification of combination products is addressed in separate policy documents, “Policy on Drug/Medical Device Combination Products - Decisions” and “Drug/Medical Device Combination Products”, which can be found on the Health Canada website.

1.4 Definitions

The following key terms are found within the risk classification rules. Their definitions are the same as those in the *Medical Devices Regulations* unless otherwise indicated.

ACTIVE DEVICE - means a medical device that depends for its operation on a source of energy other than the 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 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 an illness or injury or a symptom of an illness or injury.

BODY ORIFICE - means a natural opening or a permanent artificial opening in the body, such as a stoma.

CENTRAL CARDIOVASCULAR SYSTEM - means the heart, pericardium, pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, common carotid arteries, cerebral arteries, brachycephalic artery, aorta, inferior and superior vena cava, renal arteries, iliac arteries and femoral arteries.

CENTRAL NERVOUS SYSTEM - means the brain, meninges, spinal cord and cerebrospinal fluid.

CLOSED-LOOP SYSTEM - in respect of a medical device, means a system that enables the device to sense, interpret and treat a medical condition without human intervention.

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.

MEDICAL DEVICE - means a device within the meaning of the *Food and Drugs Act*, but does not include any device that is intended for use in relation to animals.

DEVICE (*Food and Drugs Act*) - means an instrument, apparatus, contrivance or other similar article, or an *in vitro* reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in

- (a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,
- (b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,
- (c) diagnosing pregnancy in human beings or animals,
- (d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or
- (e) preventing conception in human beings or animals;

however, it does not include an instrument, apparatus, contrivance or article, or a component, part or accessory of any of them, that does any of the actions referred to in paragraphs (a) to (e) solely by pharmacological, immunological or metabolic means or solely by chemical means in or on the body of a human being or animal.

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.

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.

2.0 GUIDANCE FOR IMPLEMENTATION

The manufacturer should first determine that their product meets the definition of a medical device as defined in the Regulations. Once confirmed, the classification rules should be applied to determine its proper risk classification.

The rules for non-IVDD medical devices can be grouped into four sets:

1. Invasive Devices (Rules 1 - 3)
2. Non-invasive Devices (Rules 4 - 7)
3. Active Devices (Rules 8 - 12)
4. Special Rules (Rules 13 - 16)

2.1 Application of the Rules

The first step in determining the risk classification of a device is to review Special Rules 13 to 16. If the device in question is not described by one of these Special Rules, then the manufacturer should determine whether the device is invasive, non-invasive, or active. There will be situations where a device is both non-invasive and active, or invasive and active, and it is not unusual for more than one rule to apply to any given device. In these situations, the final classification will be determined by the rule which assigns the higher risk.

It is the manufacturer's intended use of the device that primarily determines the device's classification. For example, an oximeter intended by the manufacturer to be used to obtain a spot-check or single measurement of arterial oxygen saturation as part of a routine examination is Class II by Rule 10(1), while a pulse oximeter intended to be used in the operating room to continuously monitor arterial oxygen saturation is Class III by Rule 10(2), and an intracardiac oximeter is Class IV by Rule 1(2). Another example is an ECG machine intended only to be used in a doctor's office for routine check-ups versus an ECG machine intended to be used in critical care settings. The former is Class II by Rule 10(1), and the latter is Class III by Rule 10(2). If a physician uses a device in a manner not intended by the manufacturer, this does not change the classification of the device.

2.2 Explanation of the Rules

Each section begins with general principles, followed by a reproduction of the rules as they are presented in the Regulations, and a detailed explanation with examples when applicable. Please note, however, that even if a particular device type is provided as an example, this does not mean that the classification indicated by the example applies to all such devices. The manufacturer is responsible for classifying their device based on its characteristics and intended purposes.

A graphical depiction of the rules is included in the Appendices.

2.2.1 Invasiveness

A device which comes into contact with the surface of the eye, or which penetrates inside the body (in whole or in part), either through a body orifice or through the surface of the body, is an invasive device. A body orifice may be either a natural opening or a permanent artificial opening in the body. A surgically invasive device always implies that it enters the body through an artificially created opening. This can be a large opening, such as a surgical incision, or a pinprick opening created by a needle. Therefore, surgical gloves and needles used with syringes are surgically invasive.

There are two exceptions to this interpretation:

- A surgically created stoma is considered, for classification purposes, to be a body orifice. Therefore, devices introduced into a stoma are not surgically invasive. In contrast, a surgically created opening to allow access to the circulatory system is not considered to be a body orifice. Devices introduced into such an opening are surgically invasive.
- A device that administers energy to the body is not invasive if only energy penetrates the body and not the device itself. Energy, as such, is not a device and therefore cannot be classified. Only the device generating or administering the energy can be classified. However, if a device administers a substance, whether this substance is a medicine or a medical device, such a substance must be assessed in its own right [for example (e.g.) substances administered by a jet injector].

2.2.1.1 Invasive Device Rules

Rule 1: (1) Subject to subrules (2) and (3), all surgically invasive devices are classified as Class II.

(2) A surgically invasive device that is intended to diagnose, monitor, control or correct a defect of the central cardiovascular system or the central nervous system or of a fetus *in utero* is classified as Class IV.

(3) A surgically invasive device that is intended to be absorbed by the body, or that is normally intended to remain in the body for at least 30 consecutive days, is classified as Class III.

Rule 1 starts by classifying all surgically invasive devices as Class II. For example, all surgically invasive disposable surgical instruments, such as single use scalpels, are Class II by this rule. Other examples are:

- Short term, intravascular catheter
- X-ray detectable, non-absorbable internal sponge
- Vascular occluder
- Suturing needle
- Surgical glove

Rule 1 then introduces the corollary that if the device is intended to diagnose, monitor, control or correct a defect of the central cardiovascular system or the central nervous system or of a fetus *in utero*, it is a Class IV device. Examples of such Class IV devices are:

- Intra-aortic valvuloplasty balloon catheter
- HIS bundle detector
- Implanted spinal cord stimulators for pain relief
- Mechanical heart valve
- Fetal pH monitor

The second corollary to Rule 1 is that a surgically invasive device that is intended to be absorbed by the body, or that is normally intended to remain in the body for at least 30 consecutive days, is Class III. Examples of such devices are:

- Peritoneal, long-term indwelling catheter
- Intraocular lens
- Pancreatic stent
- Shoulder prosthesis
- Absorbable, synthetic, polyglycolic acid suture
- Dental cement
- Tooth shade resin material

Rule 2: (1) Subject to subrules (2) to (4), all invasive devices that penetrate the body through a body orifice or that come into contact with the surface of the eye are classified as Class II.

(2) A device described in subrule (1) that is intended to be placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum is classified as Class I.

(3) A device described in subrule (1) that is normally intended to remain in the body or in contact with the surface of the eye for at least 30 consecutive days is classified as Class III.

(4) A device described in subrule (1) that is intended to be represented as preventing the transmission of infectious agents during sexual activities or reducing the risk thereof is classified as Class III.

Similar to Rule 1, Rule 2 states that all devices that penetrate the body through a body orifice or that come into contact with the surface of the eye are Class II. Examples of such devices are:

- Laryngoscope (both rigid and non-rigid)
- Urethral catheter
- Daily wear, soft contact lenses
- Single use vaginal dilator
- Tracheostomy tube
- Examination glove

Rule 2 then introduces the corollary that if such an invasive device is placed in the oral or nasal cavities as far as the pharynx or in the ear canal up to the ear drum, they are Class I. Examples of such devices are:

- Nasopharyngeal airway
- Tympanoscope
- Intra-nasal septal splint
- Dressing for nose bleed
- Manual toothbrush

The second corollary to Rule 2 states that when a device is invasive via a body orifice, or that is in contact with the surface of the eye, and remains so for 30 consecutive days or longer, it is a Class III device. Examples of devices that fall under this corollary are:

- Intrauterine contraceptive device (IUD) and introducer
- Ureteral stent

The third corollary to Rule 2 states that if the device is intended to prevent the transmission of infectious agents during sexual activities (or to reduce the risk thereof), it is a Class III device. Examples of such devices are:

- Female condom
- Non-latex condom
- Dental/oral barrier dam (intended for use during sexual activities)

Rule 3: Despite rules 1 and 2

- (a) all denture materials and orthodontic appliances, and their accessories, are classified as Class II;**
- (b) all surgical or dental instruments are classified as Class I; and**
- (c) all latex condoms are classified as Class II.**

Rule 3 overrides Rules 1 and 2 and is a “special” rule for invasive devices.

The first corollary places denture materials and orthodontic appliances, and their accessories, in Class II. Examples of devices that are Class II by this rule are:

- Orthodontic metal bracket
- Orthodontic bracket adhesive resin and tooth conditioner
- Denture repair kit
- Preformed denture (partially prefabricated denture)
- Plastic teeth

The second corollary to this rule states that all surgical or dental instruments are classified as Class I. In order for a medical device to be considered a “surgical or dental instrument” and, therefore, be classified as a Class I device, it must meet all of the following criteria:

1. It is intended for use during a surgical or dental procedure and is generally not an accessory to another medical device (e.g., orthopedic implant trial);
2. It is reusable [that is (i.e.), not disposable/single use];
3. It is not connected to an active/powered device; and
4. It is intended to be used to perform one of the following actions: cutting, drilling, sawing, scraping, clamping, hammering, puncturing, dilating, retracting or clipping.

Examples of reusable and manual instruments that fall under this corollary are:

- Adenotome
- Intestinal (clamps) forceps

- Urethral dilator
- Periodontic scaler

An instrument that is intended for surgical or dental use that does not meet all of the criteria indicated above would, most likely, be Class II by either Rule 1(1) or 2(1).

The third corollary to Rule 3 states that all latex condoms are Class II.

2.2.1.2 Non-Invasive Device Rules

Rule 4: (1) Subject to subrule (2), all non-invasive devices that are intended to come into contact with injured skin are classified as Class II.

(2) A device described in subrule (1) that is intended to be used as a mechanical barrier, for compression or for absorption of exudations is classified as Class I.

Rule 4 classifies non-invasive devices that come into contact with injured skin, where they are intended to be used only as mechanical barriers, for compression or for absorption of exudations, as Class I. Examples of devices that are Class I by this rule are:

- Gauze bandage
- Burn sheet

Non-invasive devices with any other intended mechanism of action or indication (e.g., promote healing, provide relief of pain, provide a moist wound healing environment), and which come into contact with injured skin, are Class II. Examples of such devices are:

- Hydrogel wound and burn dressing
- Alginate antimicrobial wound dressing

Rule 5: A non-invasive device intended for channelling or storing gases, liquids, tissues or body fluids for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class II.

Rule 5 covers non-invasive devices intended for channelling or storing gases, liquids, tissues or body fluids for the purpose of introduction into the body by means of infusion or other means of administration, and classifies them as Class II. Devices classified under this rule must be considered separately from devices covered under Rule 7, which have either no physical contact with the patient or only come into contact with intact skin.

Devices covered under Rule 5 may be considered indirectly invasive, meaning that they are generally attached to an invasive device (e.g. an IV administration set is attached to an introductory needle).

Typically, devices addressed by this rule are used in transfusion, infusion, extracorporeal circulation, and the delivery of anaesthetic gases and oxygen. In some cases, devices covered under this rule are simple gravity-activated delivery devices. Examples of devices that fall under Rule 5 are:

- Ventilator tubing and support set
- Piston syringe
- Enteral feeding bag
- Anaesthesia flowmeter
- Oxygen mask
- Elastomeric infusion pump

Rule 6: (1) Subject to subrules (2) and (3), a non-invasive device intended for modifying the biological or chemical composition of blood or other body fluids, or liquids, for the purpose of introduction into the body by means of infusion or other means of administration is classified as Class III.

(2) A device described in subrule (1) whose characteristics are such that the modification process may introduce a foreign substance into the body that is potentially hazardous, taking into account the nature and quantity of the substance, is classified as Class IV.

(3) A device described in subrule (1) that accomplishes the modification by centrifugation, gravity filtration or the exchange of gas or heat is classified as Class II.

Rule 6 covers the more sophisticated elements of extracorporeal circulation sets, dialysis systems and autotransfusion systems, as well as devices for extracorporeal treatment of body fluids which may not be reintroduced immediately into the body.

Rule 6(1) states that non-invasive devices intended to modify the biological or chemical composition of blood or other body fluids, or liquids, for the purpose of introduction into the body by means of infusion or other means of administration are Class III. Examples of devices that are classified under this rule are:

- Automatic delivery peritoneal dialysis system
- Hollow fiber capillary dialyzer
- Water purification/reverse osmosis system

Many devices involved in dialysis and hemoperfusion are also covered under Rule 11(2). However, both Rule 11(2) and Rule 6(1) classify them as Class III.

The first corollary to this rule addresses those devices which, during the modification process, may introduce into the body a foreign substance that is potentially hazardous, taking into account the nature and quantity of the substance. Certain stem cell separators and ex vivo photodynamic cell processors are Class IV by this corollary.

The second corollary identifies those devices that accomplish the intended modification through centrifugation, gravity filtration or the exchange of gas or heat as Class II. Examples of devices of this nature are:

- Cardiopulmonary bypass cardiectomy suction line blood filter
- Cardiopulmonary bypass heat-exchanger
- Anaesthetic conduction filter

Rule 7: (1) Subject to subrule (2), all other non-invasive devices are classified as Class I.

(2) A device described in subrule (1) is classified as Class II if it is intended:
(a) to act as a calibrator, tester or quality control support to another medical device; or
(b) to be connected to an active device that is classified as Class II, III or IV.

Rule 7(1) is a fallback rule intended to cover all other non-invasive devices not addressed by a more specific rule. Examples of devices which are Class I by Rule 7(1) are:

- Manual, adjustable hospital bed
- Leg prosthesis
- Hand splint
- Mechanical wheelchair

Devices covered under this rule have either no physical contact with the patient or only come into contact with intact skin. These devices may, however, be connected to the patient by means of a catheter or other tubing.

There are two corollaries to Rule 7. The first states that should the device act as a calibrator, tester or quality control support to another medical device, it is classified as Class II. Only calibrators, testers and quality control support devices offered for sale as part of medical device systems or as medical devices themselves fall under this category. These calibrators and testers must be employed to calibrate or test a medical device prior

to (or during every use) in order to ensure the proper functioning of the device. Equipment used to repair a malfunctioning device is not considered to be a calibrator or tester for the purpose of this rule. This rule also does not include equipment used for periodic servicing and maintenance of a device. Moreover, calibrators and testers used during the manufacturing of a device are not considered to be medical devices themselves.

Examples of devices that are classified under Rule 7(2)(a) are:

- Pacemaker generator function analyzer
- Anaesthesia unit calibrator
- Gas pressure calibrator
- Dialysis unit test equipment
- Radiographic test pattern

The second corollary to this rule states that if a device described in Rule 7(1) is intended to be connected to an active device that is classified as Class II or higher, then it becomes a Class II device. For instance, an electrode for a transcutaneous electrical nerve stimulator (TENS) is not an active device but, rather is connected to an active Class II device (i.e., TENS unit). Such an electrode is a Class II medical device under Rule 7(2)(b). Examples of other devices that fall under this rule are:

- Gas pressure transducer
- Transcutaneous oxygen electrode
- Heart sound transducer
- Tens cable/lead
- Electrosurgical unit cable adaptor

2.2.2 Active Devices

An “active device” requires a source of energy (other than the energy generated by the human body or gravity) to work. Medical devices using pre-stored gases or vacuum as a power source are regarded as active devices. Examples of such devices include vacuum powered body fluid suction units and gas powered suction pumps. Radioactive sources that are intended to deliver ionizing radiation are also considered to be active devices. Digital thermometers depend on a source of energy to operate and are, thus, active devices, whereas clinical mercury thermometers are not considered active devices.

A device whose function depends on gravity or energy provided by a human is not considered to be an active device. For example, intravenous administration sets rely on gravity for the flow of IV fluids and are therefore, not active devices. The application of energy from the human body does not make a device active unless that energy is stored

within the device for subsequent release. For instance, a syringe which relies on energy generated by human muscle to depress the plunger (thus causing a substance to be delivered to the patient) is not an active device. However, if a drug delivery system depends upon manual winding to preload a spring, which is subsequently released to deliver a substance, then the device incorporating the spring is considered to be an active device.

2.2.2.1 Active Device Rules

Rule 8: (1) Subject to subrules (2) and (3), an active device intended to emit ionizing radiation, including any device or software intended to control or monitor such a device or directly influence its performance, is classified as Class III.

(2) A device described in subrule (1) that is intended to be used in radiographic mode is classified as Class II.

(3) Despite subrule (2), an active device that is intended to be used for mammographies is classified as Class III.

Rule 8 deals specifically with devices intended to emit ionizing radiation. All such devices, together with any software intended to control, monitor or directly influence the performance of such devices, are classified as Class III unless they are used only in radiographic mode, in which case, they are classified as Class II. However, mammographic x-ray systems, although used in radiographic mode, are still Class III.

The following are examples of devices which emit ionizing radiation and are Class III by Rule 8(1):

- Gold, titanium or platinum isotope seed
- Angiographic x-ray system
- Bone densitometer
- Fixed radiographic/fluoroscopic unit
- Computed tomography x-ray scanner

Examples of devices that are used in the radiographic mode and are Class II by Rule 8(2) are:

- Digital dental imaging system - filmless
- Diagnostic dental radiographic unit (x-ray)

Rule 9: (1) Subject to subrules (2) and (3), an active therapeutic device, including any dedicated software, intended to be used to administer or withdraw energy to or from the body is classified as Class II.

(2) If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III.

(3) A device described in subrule (2) that is intended to control the treatment of a patient's condition through a closed loop system is Class IV.

Rule 9(1) classifies all active therapeutic medical devices intended to be used to administer or withdraw energy to or from the body, together with any dedicated software, as Class II. Examples of devices that are Class II by Rule 9(1) are:

- Air pressure tourniquet
- Powered traction unit
- Air-powered dental hand-piece
- Non-invasive bone-growth stimulator
- Air conduction hearing-aid
- Powered toothbrush
- Transcutaneous electrical nerve stimulator for pain relief

Rule 9(2) states that if the administration or withdrawal of energy by a device described in Rule 9(1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the intensity of the energy and the part of the body concerned, the device is classified as Class III. Examples include therapeutic intense pulsed light (IPL) or laser (Class 3B or Class 4 as per IEC 60825-1) devices intended for photocoagulation of vascular lesions and hair removal. Examples of other devices which are Class III by Rule 9(2) are:

- Electroanesthesia apparatus
- High energy DC defibrillator (including paddles; non-closed loop)
- Electroconvulsive therapy device
- Cyclodestructive ultrasound device
- Surgical neodymium YAG laser
- Hyperbaric chamber
- Neonatal phototherapy unit

There are devices that fall under both Rule 9(2) as Class III, and Rule 1(2) as Class IV. Such devices include: the ventricular assist device, the laser coronary angioplasty device,

and the intra-aortic and control balloon system. These are good examples of when the “highest classification possible” rule applies.

A device that meets the criteria set out in Rule 9(2) and that is also intended to control the treatment of a patient’s condition through a closed-loop system is classified as Class IV. A “closed-loop system” refers to a device that is capable of sensing, interpreting and treating a patient without human interference at any point in the procedure. Examples of devices that fulfill both these corollaries are:

- External pacemaker pulse-generator
- Automatic implantable cardioverter defibrillator
- Implantable rate responsive pacemaker
- Implanted vagus nerve epilepsy stimulator

Rule 10: (1) Subject to subrule (2), an active diagnostic device, including any dedicated software, that supplies energy for the purpose of imaging or monitoring physiological processes is classified as Class II.

(2) A device described in subrule (1) that is intended to be used to monitor, assess or diagnose a disease, a disorder, an abnormal physical state or a pregnancy, if erroneous readings could result in immediate danger, is classified as Class III.

Rule 10(1) classifies all active diagnostic devices, including any dedicated software, that supply energy for the purpose of imaging or monitoring physiological processes, as Class II. Examples of devices which fall under this rule are:

- Phonocardiograph
- Long term, portable ECG recorder (holter monitor)
- Evoked response photic stimulator
- Infrared thermometer
- Audiometer
- Non-indwelling blood pressure monitor
- Electronic stethoscope

However, there is also a corollary to Rule 10 which is similar to that of Rule 9. It classifies devices described in Rule 10(1) that are intended to be used to monitor, assess or diagnose a disease, a disorder, an abnormal physical state, or a pregnancy, where erroneous readings could result in immediate danger, as Class III. Examples of devices which are Class III by Rule 10(2) are:

- Nitrous-oxide gas analyser (gaseous phase)

- Ultrasonic/doppler neonatal blood pressure monitor
- Cardiac monitor (including cardiometer and rate alarm)
- Arrhythmia detector and alarm
- Neonatal heart rate monitor
- Ultrasonic blood flow monitor

There are instances when a device is classified as both a Class III by Rule 10(2) and Class IV by Rule 1(2). However, given that Rule 1(2) assigns the higher risk, the final classification of such a device is Class IV. Examples include: an intracardiac oximeter, thermal diffusion cerebral blood flow monitor, and fetal pH monitor.

Rule 11: (1) Subject to subrules (2) and (3), an active device, including any dedicated software, intended to administer drugs, body fluids or other substances to the body or withdraw them from the body is classified as Class II.

(2) If the administration or withdrawal by a device described in subrule (1) is potentially hazardous, taking into account the nature of the administration or withdrawal, the nature of the substance involved and the part of the body concerned, the device is classified as Class III.

(3) A device described in subrule (2) that is intended to control the treatment of a patient's condition through a closed loop system is classified as Class IV.

Rule 11 covers active devices that administer or withdraw substances to or from the body. Examples of such devices are drug delivery systems, anaesthesia equipment, infusion pumps, and suction units.

Rule 11(1) states that an active device, including any dedicated software, intended to administer or withdraw drugs, body fluids or other substances to or from the body is classified as Class II. Examples of devices that are classified under this rule are:

- Nebulizer (direct patient interface)
- Biopsy suction instrument
- Infant aspirator (battery-powered)
- Hysteroscopic insufflator
- Suction operatory unit
- Oral irrigating unit

The first corollary to this rule states that should the administration or withdrawal by such a device be potentially hazardous, taking into consideration the nature of the administration or withdrawal, the nature of the substance involved and the part of the

body concerned, the device is classified as Class III. Examples of devices that are classified as Class III by Rule 11(2) are:

- Antichoke suction device
- Hemoperfusion sorbent apparatus
- Volume ventilator (critical care)
- Semi-automatic peritoneal dialysate delivery system
- Insulin infusion pump
- Anesthesia gas machine

If a device meets the criteria set out in the first corollary and is intended to control the treatment of a patient's condition through a closed-loop system, it is classified as Class IV by Rule 11(3). A closed-loop blood glucose controller is an example of such a device.

Rule 12: Any other active device is classified as Class I.

Similar to Rule 7 for non-invasive devices, rule 12 acts as a fall-back rule for active devices. This rule is intended to catch all active medical devices not addressed by Rules 8 through 11, and classifies them as Class I. Examples of devices that are Class I by Rule 12 are:

- Intraoral dental light
- AC-powered keratoscope
- Powered external limb component (hand)
- Hydraulic adjustable hospital bed
- Powered wheelchair

Although a device may be Class I by Rule 12, other applicable rules may move the device to a higher classification. For example, a portable leakage current alarm is Class I by Rule 12, but Class II by Rule 7(2)(a). Again, it is important to check all rules.

2.2.3 Special Devices Rules

Rules 13 - 16 were developed to address certain issues related to medical devices.

Rule 13: A medical device that is intended to be used for

- (a) disinfecting or sterilizing blood, tissues or organs that are intended for transfusion or transplantation is classified as Class IV; and**
- (b) disinfecting or sterilizing a medical device is classified as Class II.**

Rule 13(a) states that a device that is intended to disinfect or sterilize blood, tissues or organs that are intended for transfusion or transplantation, is classified as Class IV.

A device that is intended to disinfect or sterilize another medical device is classified as Class II by Rule 13(b). Examples of devices that fall under this rule are:

- Steam sterilizer (autoclave)
- Dry heat sterilizer
- Ultraviolet sterilizer

Rule 14: (1) Subject to subrule (2), the following medical devices are classified as Class IV:

(a) a medical device that is manufactured from or that incorporates human or animal cells or tissues or their derivatives; and

(b) a medical device that is manufactured from or that incorporates a product produced through the use of recombinant DNA technology.

(2) A device described in subrule (1) that is intended to come into contact with intact skin only is classified as Class I.

Rule 14(1) states that a medical device that is manufactured from (or that incorporates) animal or human cells or tissues or their derivatives, or is manufactured from (or that incorporates) a product produced through the use of recombinant DNA technology, is classified as Class IV. Examples of devices that are Class IV by Rule 14(1)(a) or 14(1)(b) are:

- Collagen corneal shield
- Tissue heart valve
- Lyophilized human dura mater
- Bone graft
- Hyaluronic acid (animal sourced) dermal filler

However, a device described in Rule 14(1) that is intended to only come into contact with intact skin is classified as Class I. An example is a leather strap on a leg brace.

Rule 15: Any medical device that is a material that is intended to be sold to a healthcare professional or dispenser for the specific purpose of configuration or arrangement into a mould or shape to meet the needs of an individual is classified in the class that applies to the finished medical device.

Rule 15 covers any medical device that is a material intended to be sold to a healthcare professional or dispenser for configuration or arrangement into a mould or shape to meet

an individual's needs. Such a device is classified in the class that applies to the finished medical device. Examples of devices that are classified under this rule are:

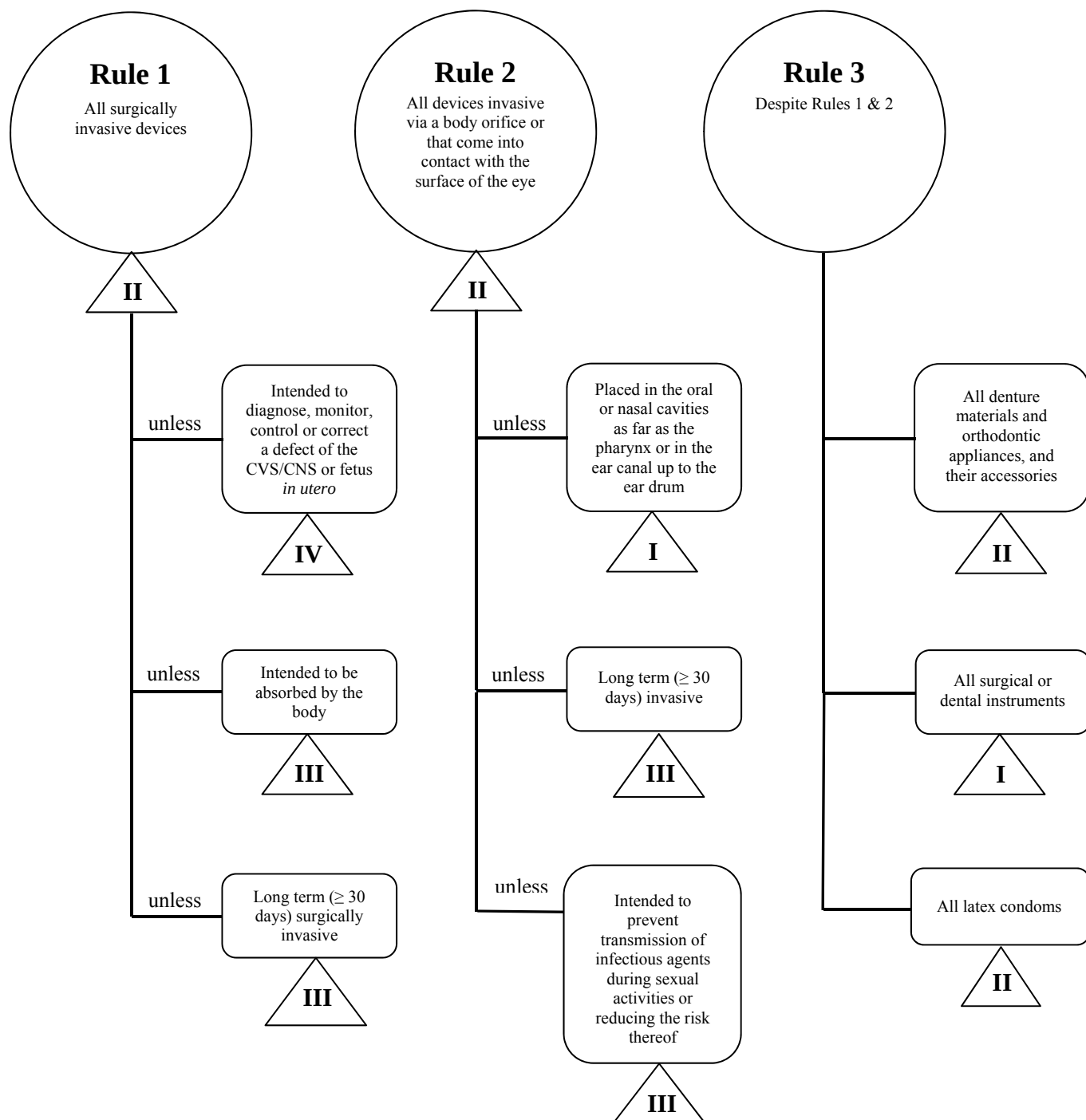
- Acrylic polymer blocks used in the formation of dentures
- Silicone sheets used in reconstructive surgery
- Glass used in the formation of lenses
- Silicone blocks used to create plastic surgery implants
- Noble metal alloy used in the fabrication of crown and bridge restorations

Rule 16: Despite rules 1 to 15, a medical device set out in column 1 of an item of the table to this rule is classified as the class set out in column 2 of that item.

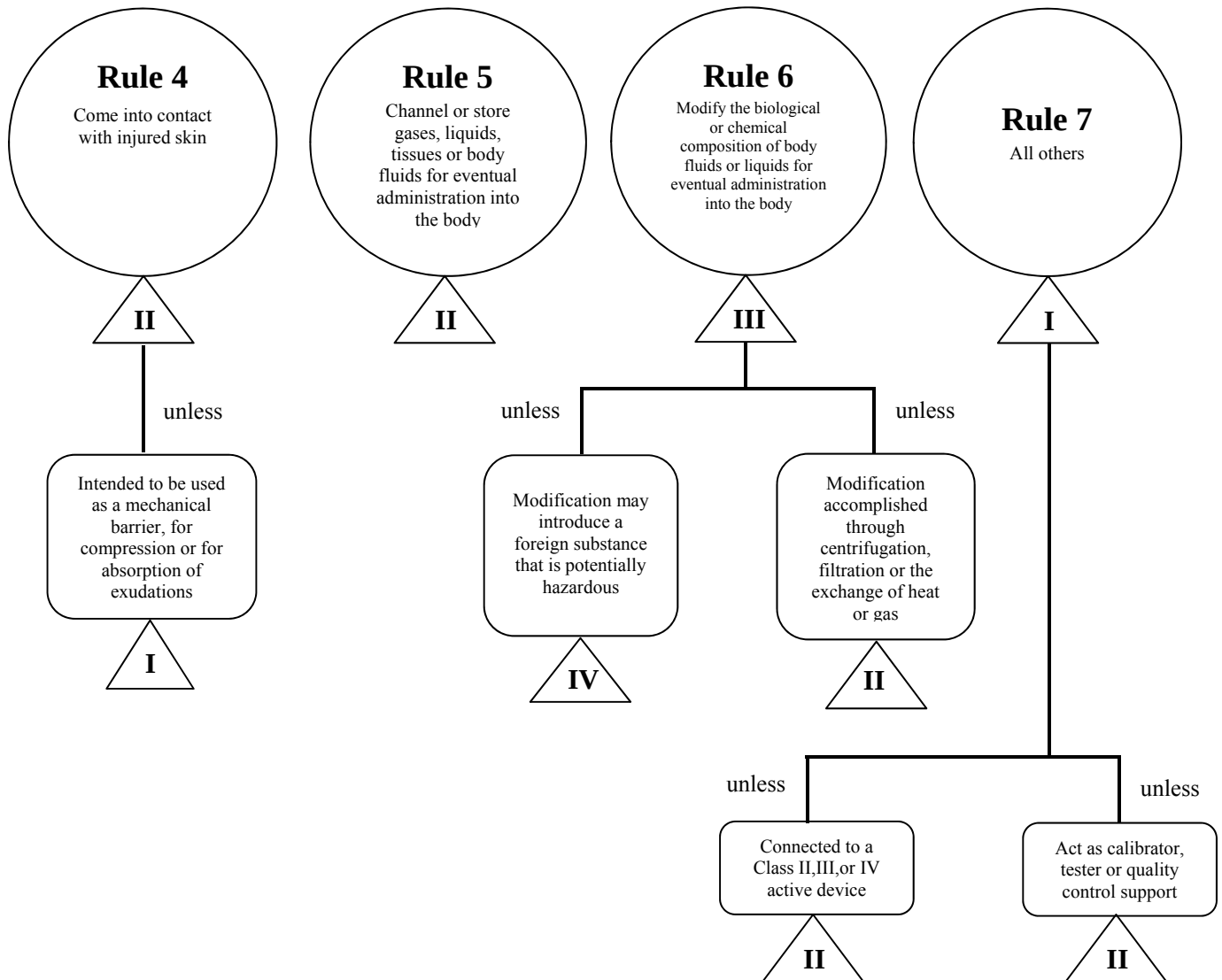
Item	Column 1 Medical Device	Column 2 Class
1.	Breast implants	IV
2.	Tissue expanders for breast reconstruction and augmentation	IV

3.0 APPENDICIES

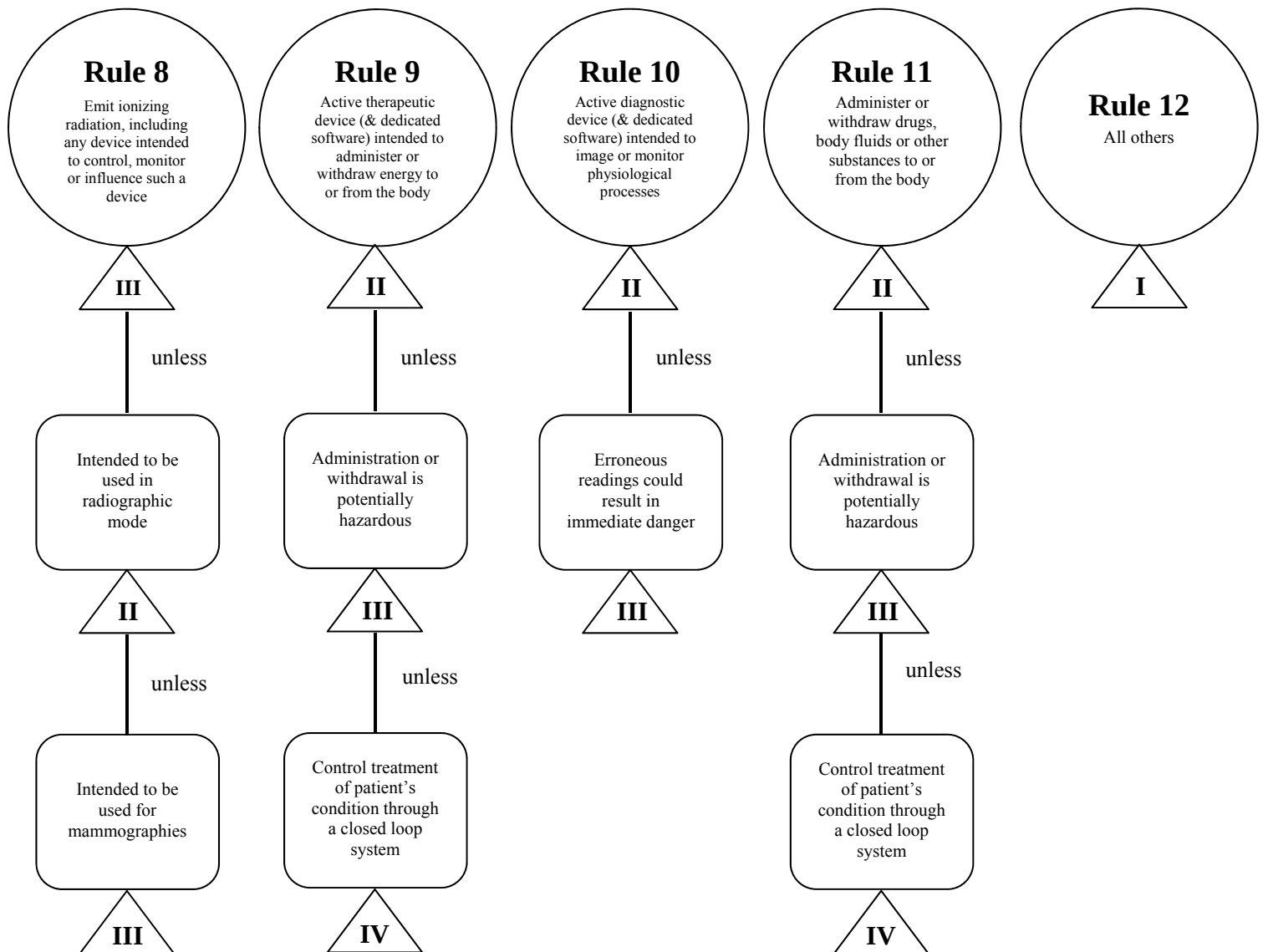
INVASIVE DEVICES



NON-INVASIVE DEVICES



ACTIVE DEVICES



SPECIAL RULES

