Health Canada Product Classification Rules

Phototherapy Eye Mask

Rule	**Invasive Devices**	**Applies**	
1:	(1) Subject to subrules (2) and (3), all surgically invasive devices are classified as Class II	Y	N
	(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.		N
	(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.		N
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 IL CRC.. c. 871 30		N
	(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 car drum is classified as Class I.		N
	(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.		N
	(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.		N
3:	Despite rules 1 and 2 (a) all denture materials and orthodontic appliances, and their accessories, are classified as Class 1I;		N
	(b) all surgical or dental instruments are classified as Class I; and		N
	(c) all latex condoms are classified as Class 11 Non-invasive Devices		N
4:	(1) Subject to subrule (2), all non-invasive devices that are intended to come into contact with injured skin are classified as Class IL		N
	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 II		N
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.		N
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		N
	(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.		N
	(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		N
	1) Subject to subrule (2), all other non-invasive devices are classified as Class I	Y	Y

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7:	(2) A device described in subrule (1) is classified as Class II if it is intended	N	N
	(a) to act as a calibrator, tester or quality control support to another medical device; or	N	N
	(b) to be connected to an active device that is classified as Class II, III or IV.	N	N
	Active Devices	N	N
8:	(I) 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		N
	(2) A device described in subrule (I) that is intended to be used in radiographic mode is classified as Class II		N
	(3) Despite subrule (2), an active device that is intended to be used for mammographies is classified as Class III.		N
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		N
	(2)1f 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.		N
	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		N
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 11.		N
	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		N
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 (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.	N	
	(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		N
12:	Any other active device is classified as Class I	N	N
	Special Rules	N	N
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.		N

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Rule 14:	(1) Subject to subrule (2), any medical device manufactured. from or incorporating non-viable or viable animal or human tissue or their derivatives, or a product produced through -the use of recombinant DNA technology, is classified as Class IV.		N
	(2) A device described in subrule (1) that is intended to come into contact with intact skin only is classified as Class 1.		Y
15:	Any medical device that is a material intended to be sold to a health care 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.		N
16:	Despite rules 1 to 15, a medical device set out in column I of an item of the table to this rule is classified as the class set out in column 2 of that item.		N
	PART 2 **IN VITRO DIAGNOSTIC DEVICES** Use with respect to Transmissible Agents		N
1:	An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, tissues or organs to assess their suitability for transfusion or transplantation is classified as Class IV.		N
2:	An IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent is classified as Class II, unless (a) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease if there is a risk of propagation in the Canadian population, in which case it is classified as Class IV; or		N
	(b) it falls into one of the following categories, in which case it is classified as Class III: (i) it is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a serious disease where there is a risk of propagation in the Canadian population, (ii) it is intended to be used to detect the presence of, or exposure to, a sexually transmitted agent, (iii) it is intended to be used to detect the presence of an infectious agent in cerebrospinal fluid or blood, or (iv) there is a risk that an erroneous result would cause death or severe disability to the individual being tested, or to the individual's offspring.		N
3:	An IVDD that is intended to be used for patient management is classified as Class II, unless it falls into one of the following categories, in which case it is classified as Class DI: (a) it is intended to be used for the management of patients suffering from a life-threatening disease; or		N
	(b) there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient.		N
	Other Uses	N	N
4:	An IVDD that is not subject to rules 1 to 3 and that is intended to be used in diagnosis or patient management is classified as Class II, unless it falls into one of the following categories, in which case it is classified as Class III: (a) it is intended to be used in screening for or in the diagnosis of cancer; (b) it is intended to be used for genetic testing;		N

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	(c) it is intended to be used in screening for congenital disorders in the fetus; (d) there is a risk that an erroneous diagnostic result would cause death or severe disability to the patient being tested or to that patient's offspring; (e) it is intended to be used for disease staging; or (f) it is intended to be used to monitor levels of drugs, substances or biological components, if there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient		
5:	An IVDD that is intended to be used for blood grouping or tissue typing to ensure the immunological compatibility of blood, blood components, tissue or organs that are intended for transfusion or transplantation is classified as Class III.		N
	Special Rules	N	N
6:	A near patient IVDD is classified as Class III		N
7:	In cases where an IVDD, including its analysers, reagents and software, is intended to be used with another IVDD, the class of both IVDDs will be that of the IVDD in the class representing the higher risk.		N
8:	If rules 1 to 7 do not apply, all other IVDDs are classified as Class I.		N
9:	Despite rules I to 8, an IVDD set out in column I of an item of the table to this rule is classified as the class set out in column 2 of that item.		N

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15/10/2013