Classification Guidance

Medical devices are classified according to Health Canada's risk-based system. There are four device classifications (Class I, II, III and IV), which are classified using a set 16 rules. In vitro diagnostic devices (IVDDs) are also classified as Class I through IV using a set of 9 rules. All classification rules may be found here.

Please note that it is the **responsibility** of the **manufacture**r to apply the Medical Devices Regulations (MDR) Classification Rules to determine the appropriate classification for their device in Canada. If need be, Health Canada can provide assistance in verifying a manufacturer's classification. 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.

We have the following documents that may assist with classifying your product:

1. Risk Classification of non-IVDDs
2. Risk Classification of IVDDs
3. Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices
4. Medical Devices Active Licence Listing (MDALL)

We have prepared a FAQ, which includes common classification decisions for medical devices used in the COVID-19 pandemic.

Classification of COVID-19 Diagnostic Test Kits

How are COVID-19 diagnostic test kits classified?
Test kits intended for the detection of COVID-19 are classified as Class IV medical devices by IVDD Rule 2(a) of the MDR Classification Rules until such time that more data are available.

How are quality controls, calibators, etc. that are intended to be used with a COVID-19 test kit classified?
Controls and calibrators intended to be used with COVID-19 test kits are considered to be Class IV medical devices by IVDD Rule 7. As per this rule, quality controls intended to be used with a Class IV test kit would also be regulated as Class IV medical devices. This is clearly outlined in our guidance document on the Risk Classification of IVDDs.

How are COVID-19 probes & primers classified?
Probes and primers typically fall under the definition of analyte specific reagents (ASRs). As per our guidance document on the Risk Classification of IVDDs, ASRs are defined as reagents such as antibodies

(monoclonal or polyclonal), proteins, primers and probes which are used as critical components in laboratory developed tests. These devices are sold without specific analytical and performance claims.

As such, ASRs specific to COVID-19 would be classified as Class II medical devices by IVDD Rule 2 of the MDR Classification Rules.

Classification of swabs

Swabs may be classified as Class I or Class II medical devices as per the Medical Devices Regulations (MDR) Classification Rules.

- A swab that is strictly 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 by Rule 2(2). These swabs are specifically represented as nasopharyngeal (NP), oropharyngeal (OP), oral, or buccal swabs.

- If swabs do not have a specific intended use statement, it can be assumed that they may be used in other body orifices. As the swab could be used to penetrate other body orifices for the collection of tissue samples (i.e. tissue sampling to test for chlamydia or ureaplasma), it would be classified as a Class II device by Rule 2(1).

Classification of viral or universal transport media (VTM/UTM)

The Global Medical Device Nomenclature (GMDN) Agency has the following definitions of various transport media:

> **Viral transport medium IVD (Code: 58697)**
> A vessel containing transport medium intended to be used for the preservation and transport of viral culture isolates from a clinical specimen.
>
> **Cell culture medium IVD (Code: 58567)**
> A liquid based tissue culture medium containing essential nutrients, sugars, amino acids and growth factors, intended to be used for the in-vitro maintenance, sustenance, and cultivation of human cells from a clinical specimen for diagnostic purposes.
>
> **Nasopharyngeal specimen container IVD, viral inactivation medium (Code: 65001)**
> A covered plastic receptacle containing a viral inactivation medium intended to be used for the collection, and/or transport of a nasopharyngeal specimen for subsequent in vitro diagnostic testing procedures [e.g., nucleic acid technique (NAT)]; it may in addition include a nasopharyngeal swab. The medium is intended to inactivate pathogenic viruses [e.g., severe acute respiratory syndrome 2 (SARS-CoV-2), the causative agent of COVID-19] in a clinical specimen. This is a single-use device.

Viral transport media (VTM) or universal transport media (UTM) may be classified as Class I or Class II:

- Media that are strictly intended to stabilize and maintain the viability of suspected pathogens or microbial constituents contained in patient specimens while in transit from the specimen collection area to the laboratory are classified as Class I devices by IVDD Rule 8. This would include GMDN Code 58697 and 58567.

- Media that are intended to collect and extract microbial constituents (e.g. nucleic acids, proteins) from human specimens for further molecular testing are classified as Class II devices by IVDD Rule 2.

- Media that contain substances intended to inactivate viruses (e.g. guanidinium/guanidine thiocyanate or similar chemicals) are classified as Class II devices by IVDD Rule 2. This would include GMDN Code 65001.

- Media intended for RNA/DNA extraction and purification of nucleic acids or proteins for subsequent molecular analysis RT-PCR analysis are classified as Class II devices by IVDD Rule 2.

Swabs/media intended to be used with a specific test kit (e.g. SARS-CoV-2)

As per IVDD Rule 7, if a swab and/or medium are represented to be used with a specific test kit (e.g. SARS-CoV-2), the swab and/or medium would take on the classification of the test kit itself. For example, SARS-CoV-2 tests kits are classified as Class IV devices. Therefore, swabs and/or media represented for use with a specific SARS-CoV-2 test kit would also be classified as Class IV as per IVDD Rule 7.

Classification of swab & media kit examples

Swabs and media are often packaged together. As per Section 7 of the MDR, if a medical device can be classified into more than one class, the class representing the higher risk applies. Some examples for clarity have been provided below:

- A swab that is not clearly intended for NP/OP/oral/buccal use (Class II) is packaged with a VTM that is only intended to stabilize and maintain the viability of the sample (Class I). The entire kit, with these components packaged together, would be classified as Class II.

- A swab that is clearly intended for NP/OP/oral/buccal use (Class I) is packaged with a VTM that is intended for RNA/DNA extraction and purification of nucleic acids or proteins for subsequent molecular analysis RT-PCR analysis (Class II). The entire kit, with these components packaged together, would be classified as Class II.

- A swab that is clearly intended for NP/OP/oral/buccal use (Class I) is packaged with a VTM that is only intended to stabilize and maintain the viability of the sample (Class I). The entire kit, with these components packaged together, would be classified as Class I.

- A swab (either Class I or Class II) and VTM (either Class I or Class II) are packaged together, where the labelling identifies that the kit is to be used with a specific assay (e.g. SARS-CoV-2

assay). The associated swab and media kit would be classified as the same classification of the assay it is intended to be used with.

- **Note**: If swab/media are represented for use with a specific assay, this assay must be authorized with Health Canada.

Classification of Personal Protective Equipment (PPE)

Personal protective equipment (PPE) are items worn to provide a barrier to help prevent potential exposure to infectious disease.

How are PPE intended for medical purposes classified?
PPE that are sold, manufactured, or represented for medical purposes are classified as medical devices in Canada. For a list of our classification guidelines for PPE specific to COVID-19, please refer to the chart below. For more information, we recommend you review the Medical Devices Regulations (MDR) Classification Rules and our guidance document on risk classification.

Product Name	Alternative Names	Classification & Rule
Surgical gowns	Isolation gowns, medical gowns	Class I by Rule 7(1)
Respirators	Medical masks, surgical masks, surgical respirators	Class I by Rule 7(1)
Face shields	Surgical helmets, surgical face splash shields, surgical face masks	Class I by Rule 7(1)
Medical goggles	Surgical goggles	Class I by Rule 7(1)
Examination gloves	Surgical gloves, medical gloves	Class II by Rule 1(1)
Isolation chambers	N/A	Class I by Rule 7(1)

How are face coverings regulated/classified?
The requirements for importing and selling face coverings in Canada vary depending on what they are for and how they are represented for use.

Face Coverings That Are Not Regulated as Medical Devices

Face coverings provide a barrier layer to help stop respiratory droplets from coughs, sneezes and talking from travelling in the air and onto other people.

Face coverings that are manufactured, sold or represented **to promote good respiratory hygiene**, such as cough etiquette, are not regulated as medical devices. These types of face coverings are intended to help prevent the spread of germs from the wearer to their surrounding environment. They may help slow the spread of COVID-19 but they do not protect people from getting COVID-19 or any other viral or bacterial infection. Face coverings clearly labelled for use in promoting respiratory hygiene or cough etiquette can be imported and sold in Canada without authorization under the Medical Devices Regulations or the Interim Order pathway.

Some examples of respiratory hygiene claims for face coverings could be:

- Helps reduce the spread of germs
- Helps stop you from touching your nose and mouth
- For use when physical/social distancing is not possible
- Cough claims (e.g. covers your cough, cough catcher, etc.)

FAQ – Is it necessary that I label my cloth face covering with a specific claim?

No, it is not necessary. The Government of Canada has published notices which discuss the potential benefits and limitations of wearing face coverings in public settings. It may be reasonable for manufacturers to expect users to understand the intended purpose of their face covering without incorporating specific claims on the product packing or their website.

If manufacturers have reason to believe that intended users, Health Canada officials, or other stakeholders may be confused about the purpose of their face coverings, it would be prudent that they develop clear labelling that accurately describes the intended use and user population.

Face coverings without medical claims are subject to the Canada Consumer Product Safety Act (CCPSA). Under the CCPSA, there is no pre-market review or approval of products. It is the responsibility of the supplier (e.g. manufacturer, importer, retailer) to ensure that the consumer products they supply to the Canadian market comply with the CCPSA and applicable regulations. Health Canada has the authority to take post-market compliance and enforcement actions if these products are found to pose a danger to human health or safety.

Please note that several regulations under the CCPSA may apply to a specific consumer product, depending on its design, construction, contents, how it is advertised and other factors. Regulatory definitions and available guidelines should be consulted in order to identify applicable requirements under the CCPSA for a specific consumer product.

If you have questions about meeting consumer product safety requirements under the CCPSA, please email hc.ccpsa-lcspc.sc@canada.ca.

Face Coverings That Are Regulated as Medical Devices

Face coverings that are manufactured, sold, and represented to help prevent the wearer from contracting a disease, including COVID-19, are regulated as (Class I) medical devices. Face coverings with unique design features, such as the incorporation of biologic components or anti-viral materials, are also regulated as medical devices. Face coverings that are intended to offer this level of protection must be designed, manufactured and tested to be effective in blocking virus particles, which goes beyond promoting good respiratory hygiene. Labelling for these types of face coverings must contain clear statements regarding their intended use (i.e., the purpose for which the device is manufactured, sold or represented) and specific performance specifications necessary for their proper use (e.g., filtration efficiency and fluid resistance).

An example of a claim that would result in a medical device classification could be "helps protect against airborne biological particles that may cause infection and disease".

Companies wanting to sell face coverings to help prevent wearers from contracting COVID can apply for:

- a Medical Device Establishment Licence (MDEL) when their face coverings are exclusively intended for use by the general public; or
- an Interim Order Authorization when their face coverings are intended to be used by healthcare workers in healthcare environments **or** when their face coverings include unique design features, such as the incorporation of biologic components or anti-viral materials.

Classification of Thermometers and Thermal Detection Equipment

Which thermometers are regulated as medical devices by Health Canada?
Thermometers that are intended to be used to measure a patient's body temperature are considered medical devices in Canada. There is a vast range of thermometers available for sale in Canada including capillary patient thermometers, digital patient thermometers and infrared (IR) patient thermometers. The regulation of these medical devices depend on their risk-based classification.

What is the classification of thermometers?
Thermometers are regulated as either Class I or Class II medical devices in Canada depending on whether they are considered active medical devices or not. The definition of an active medical device can be found here.

Active, battery-powered thermometers
Thermometers which are active and therefore, rely on a source of energy for their operation are considered to be Class II medical devices by Rule 10(1). Examples include IR and wireless patient thermometers.

Non-active thermometers

Thermometers which are non-active and are intended to measure body temperature through the oral or ear cavity are considered to be Class I medical devices by Rule 2(2). Examples include mercury or alcohol based capillary patient thermometers.

What is thermal detection equipment?

Thermal detection equipment, such as thermal imaging cameras and thermal scanners, use a well-established technology with many applications including medical, military, industrial, and automotive. These devices work by capturing the infrared radiated energy emitted by the body and typically produce thermography maps, or thermograms, to detect elevated temperatures. During the COVID-19 pandemic, thermal detection equipment is being used as a screening tool in various locations and checkpoints such as airports, medical clinics, and grocery stores.

What is the classification of thermal detection equipment?

Thermal detection equipment that is used to detect elevated body temperature is typically classified as a Class I medical device by Rule 12 of the Medical Devices Regulations (MDR) Classification Rules.

Classification of Ventilators

Ventilators are classified as Class III medical devices by Rule 11(2). However, if the ventilator operates on a closed-loop system, it is classified as a Class IV medical device by Rule 11(3).

Classification of Disinfectants/Sterilants

Depending on the intended use/representation for use of a disinfectant and sterilizer, these products can be considered medical devices, consumer products or drugs. More information on how these products are regulated can be found in the table below.

Product	How is the product regulated?	Description/Examples
Disinfectants for use on semi-critical and critical medical devices.	The Medical Devices Directorate regulates these products as Class II medical devices under the Medical Devices Regulations.	Disinfectants to be used on ventilators and breathing circuits.
Medical device sterilizers.	The Medical Devices Directorate regulates these products as Class II medical devices under the Medical Devices Regulations.	Sterilizer machines intended to reprocess face masks and other personal protective equipment.

Skin cleansers, surface disinfectants and disinfectants for non-critical medical devices.	The Natural and Non-prescription Health Products Directorate regulates these products under the Food and Drugs Act. Please contact: hc.nnhpd-dpsnso.sc@canada.ca.	- Hand sanitizers - Surface wipes - Hard surface disinfectants

Classification of Antimicrobial Products

What antimicrobial products are considered medical devices?
Health Canada's policy on combination products specifies that combination products where the principal mechanism of action is not pharmacological, immunological, or metabolic in nature would be regulated as medical devices.

> **Example:** A face mask infused/treated with an anti-bacterial or antimicrobial agent. The primary function of the mask is to provide a physical barrier (i.e. between patient and healthcare professional, between patients, etc.), and therefore the mask would still fit the definition of a medical device and be regulated as such.

My antimicrobial product does not meet the definition of a medical device. How is it regulated?
Antimicrobial products that do not meet the definition of a medical device are typically considered to be treated articles and are regulated by the Pest Management Regulatory Agency (PMRA).

In Canada, the Pest Control Products Act (PCPA) defines a pest control product as:

a) a product, an organism or a substance, including a product, an organism or a substance derived through biotechnology, that consists of its active ingredient, formulants and contaminants, and that is manufactured, represented, distributed or used as a means for directly or indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects;

b) an active ingredient that is used to manufacture anything described in paragraph (a); or

c) any other thing that is prescribed to be a pest control product.

The term "pesticide", while not defined in the PCPA, is often used to describe a pest control product and covers a broad range of substances that are commonly known as herbicides, insecticides, rodenticides, fungicides, **antimicrobials,** etc.

For guidance on regulatory requirements for articles that have been **treated with a pesticide**, please see the following webpage.

For more information regarding pesticides and their registration, please refer to the following webpage. If you have any questions regarding pest control products/pesticides, please reach out to PMRA directly at hc.pmra.info-arla.sc@canada.ca.

My proposed product is not listed above. How can I classify my medical device?

If you require assistance in classifying your COVID-19 medical device, please provide as much of the information below as possible to the Medical Devices Directorate at hc.meddevices-instrumentsmed.sc@canada.ca.

1. **Self Classification Assessment:** Please perform your own classification assessment using the information provided in our guidance document on Risk Classification of non-IVDDs or Risk Classification of IVDDs. Please also make specific reference to the Medical Devices Regulations (MDR) Classification Rules.

2. **Device Description:** Please provide in detail the intended use (i.e., how it is represented for use, who the intended users are, etc.) of the device, as per the manufacturer. The description should include a general description of the disease(s) or condition(s) the device will diagnose, treat, prevent or mitigate, including where applicable a description of the patient population for which the device is intended. If applicable, please also describe the device's mechanism of action.

3. **Device Labelling:** This should be submitted in the form of an IFU (Instructions for Use), user manual, promotional materials, website links, etc. available for the device.

4. **International Regulatory Status:** If your product has been licensed outside of Canada, please provide a list of countries or regions where it has been licenced, and describe how it has been regulated (i.e., has it been regulated as a medical device and, if so, what risk classification has it been regulated as?).

5. **Competitor Products:** If you are aware of any competitor products licensed in Canada, please provide the respective medical device licence number.

   Please note that the Medical Devices Active Licence Listing (MDALL) allows you to search for an active Class II, III or IV Medical Device Licence using various options such as company name, licence name, device name, company ID, licence number and device identifier (e.g., reference number).

   Class I medical devices are not included in this database as they are not required to have a Medical Device Licence. However, manufacturers of Class I devices are required to hold a Medical Device Establishment Licence (MDEL). If you wish to search for holders of a MDEL, you may visit the Medical Devices Establishment Licence Listing.