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--using a set of 16 rules found in Schedule 1, Part 1 of the Canadian Medical Devices Regulations (CMDR) SOR/98-282. IVDs are also classified as Class I through IV using a set of 9 rules, which can be found in Schedule 1, Part 2 of the CMDR.

It is the **responsibility** of the **manufacture**r to apply the rules set out in Schedule 1 of the Regulations 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.

Guidance documents have been prepared to assist in the interpretation of policies and governing statutes and regulations. Here are some helpful links to assist you with your classification:

- **Medical Device Regulations:** http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/index.html
- **Guidance Document - Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs):** https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-guidance-risk-based-classification-system-non-vitro-diagnostic.html
- **Draft Guidance Document - Guidance for the Risk-based Classification System for In Vitro Diagnostic Devices (IVDDs):** https://www.canada.ca/en/health-canada/services/drugs-health-products/public-involvement-consultations/medical-devices/draft-guidance-guidance-supporting-evidence-provided-class-vitro-diagnostic-device-licence-applications-amendments-consultation.html
- **Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices:** http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/keyword_motscles2-eng.pdf
- **Medical Devices Active Licence Listing (MDALL) - Your reference tool for licensed medical devices in Canada:** https://health-products.canada.ca/mdall-limh/index-eng.jsp

Please find below general classification guidance relating to COVDID-19 devices:

COVID-19 Test Kits

As per IVDD Rule 2 of the Medical Devices Regulations (MDR) Classification Rules, an IVDD that is intended to be used to detect the presence of, or exposure to, a transmissible agent is classified as Class II. Where,

our guidance document on the Risk Classification of IVDDs specifically lists coronaviruses (with the exception of SARS) as an example of an infection detected by a Class II IVDD pursuant to this rule.

However, Note 1 in the guidance states that an agent that is linked to a global outbreak may be subject to a higher classification rule. In this case, IVDD Rule 2(b)(i) would apply, which states that if an IVDD is intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a serious disease and where there is a risk of propagation in the Canadian population, it is Class III.

At this time, the World Health Organization (WHO) has declared COVID-19 a pandemic. Therefore, test kits intended for the detection of COVID-19 would be considered Class III medical devices by IVDD Rule 2(b)(i) as the agent is linked to a current global outbreak.

Additionally, they may also fall under IVDD Rule 6 if they are near patient in nature.

Respirator (Masks)

Public and surgical respirators are **manufactured for use*** ** to prevent the transmission of disease and provide a safety barrier against contamination. They are typically used during examinations or medical procedures. Therefore, unless it is explicitly clear in the product labelling that they serve a non-medical purpose (e.g. “not for medical use”, “industrial use only”), public and surgical respirators are considered to be medical devices.

- **Public respirators*** are considered to be Class I medical devices per Rule 7(1) of Schedule 1, Part 1 of the *Medical Devices Regulations*.
- **Surgical respirators**** are considered to be Class I medical devices per Rule 7(1) of Schedule 1, Part 1 of the *Medical Devices Regulations*.

If you need further assistance to verify your classification, please submit the following information:

1. **Device description:** including the intended use (i.e., how it is represented for use, who the intended users are, etc.) of the device, as per the manufacturer is 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. The description should include all the labelled uses of the device, for example the condition(s) or disease(s) to be prevented, mitigated, treated or diagnosed, part of the body or type of tissue applied to or interacted with, frequency of use, physiological purpose, patient population and identify if the device is invasive/surgically invasive and if so for what duration of time.

2. **Device labelling:** This should be submitted in the form of Instructions for use / user manual, package/box labels, package labelling and marketing materials for the device.

3. **Manufacturer’s classification Rationale:** Please provide a comprehensive explanation of your classification assessment. Please identify which classification rule(s) was applied to determine the device’s risk classification and a rationale as to why that rule was chosen.

4. **Previous Correspondence:** Provide any previous classification of your product or any other correspondence relevant to the risk classification of the product.