

Medical Devices Classification Tool/

This tool is intended to assist you with the classification of your medical device by walking through the classification rules found in Schedule 1 of the *Medical Devices Regulations* (<https://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/FullText.html>) (the Regulations).

It is only intended to classify products that meet the definition of a “device” in the *Food and Drugs Act* (<https://laws-lois.justice.gc.ca/eng/acts/f-27/FullText.html>) and a “medical device” into Class I, II, III or IV.

It will not determine whether your product is not a medical device or if it falls under another category (e.g., drug, consumer product). You will need to determine that your product fits the definition of a “medical device” prior to using this tool.

'Click below to launch the Classification Tool'



Classification
Tool

Please note: The tool will provide classification guidance based strictly on how you answer the questions herein. This classification guidance should not be taken as a final decision by Health Canada

Guidance Documents

The following guidance documents can be consulted for definitions, examples, and for additional information on how to interpret the classification rules:

- [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) (<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>)
- [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/medical-devices/application-information/guidance-documents/guidance-document-guidance-risk-based-classification-system-vitro.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-guidance-risk-based-classification-system-vitro.html>)

For Software as a Medical Device (SaMD):

When using this tool to classify Software as a Medical Device (SaMD), please refer to the SaMD guidance documents below to understand Health Canada's interpretation of terms such as "immediate danger" in this context.

You may wish to consult the Medical Devices Directorate to confirm your SaMD classification.

- [Guidance Document Software as a Medical Device \(SaMD\): Definition and Classification \(https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document.html)
- [Guidance Document Software as a Medical Device \(SaMD\): Classification Examples \(https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance/examples.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance/examples.html)

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