



# Medical Gloves

Health Canada licenses all disposable medical examination gloves imported and sold in Canada. Here's what you need to know:

The *Food and Drugs Act* and the *Medical Devices Regulations* (the Regulations) help to protect the health and safety of Canadians. They do this by placing specific requirements and prohibitions on medical devices sold in Canada.

These include classifying medical devices into four groups (Class I, II, III and IV) based on their risk to health and safety. Class I devices present the lowest potential risk (for example [e.g.] thermometers). Class IV devices present the largest potential risk (e.g. pacemakers).

Health Canada licenses all Class II, III and IV medical devices imported, advertised and sold in Canada. Before issuing a licence, we verify that the device meets the requirements for safety and effectiveness and complies with the standards for a quality management system.

## Medical gloves are Class II medical devices

Medical gloves are used to prevent the transmission of disease and provide a safety barrier against contamination. They are typically used during examinations or medical procedures. As such, they are medical devices.

Medical gloves are classified as Class II devices. This is the case whether the gloves are made of latex, vinyl, synthetic polymer or nitrile, or are sterile or non-sterile. For example, disposable, non-sterile, polyethylene gloves in first aid kits are medical gloves. They protect both the patient and the wearer.

## Class II medical devices must be licensed

If you manufacture a Class II medical device, you must get a medical device licence from Health Canada. You cannot import or sell a Class II medical device unless the manufacturer has a medical device licence from Health Canada.

## Labels on Class II medical devices must meet regulatory requirements

The Regulations specify how to label medical devices. If you manufacture medical devices, you must clearly explain the intended use of a device if it is not obvious. You can accomplish this using specific words and images. For example:

- words such as “health care”, “examination”, “patient examination”, “sterile” or “medical grade”
- images or symbols that signify a medical use such as care, body, safe, guard, or cross

These labels are needed because not all disposable gloves are manufactured or sold for use as medical gloves. Consumers also use disposable gloves in car repair shops, homes, etc.

## Non-medical gloves must not be mistaken for medical gloves

Disposable gloves not intended for medical use are not subject to the Regulations. This means non-medical and industrial-use gloves must not give the impression they can be used for medical purposes. If they are used for medical procedures, these gloves could pose a health risk to Canadians.

## Make it clear if disposable gloves are not medical

If you manufacture non-medical disposable gloves, you must make sure the label and advertising does not say or suggest the gloves have a medical use. It is also important that the brand or company name associated with the gloves does not imply a medical use.

Manufacturers have tried to describe their gloves as “general purpose” or “multi-purpose”. But Health Canada has found that this is not clear enough. Consumers can misunderstand these words. Instead, Health Canada recommends using terms such as:

- “Industrial use only”
- “Not for medical use”
- “Not a medical device”

If you sell non-medical disposable gloves, Health Canada recommends making sure they are not placed near any health care products or sold in a medical setting such as a medical supply store. Doing so may imply the gloves have a medical use.

### Health Canada has more resources to help you

- Guidance document for labelling medical devices  
[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl\\_etiq\\_dv10-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl_etiq_dv10-eng.php)
- Medical Devices Active Licence Listing  
<http://www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic-eng.php>
- Medical device licence application forms  
<http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/form/index-eng.php>