

# Novel Coronavirus

## RCC RETAIL RECOVERY CHECKLISTS - TEMPLATES

### Regulatory Requirements for Non-medical Masks/Fashion Face Coverings – May 6, 2020

# Regulatory requirements for non-medical masks/fashion face coverings – May 6, 2020

With the high-demand for face masks, RCC has received numerous questions from retailers asking what regulatory requirements there are for selling non-medical face masks or fashionable face coverings. To help retailers navigate what they need to know regarding face masks, we have put together answers to frequently asked questions and more information requirements below.

- **What regulations should I be aware of if I want to sell non-medical masks in Canada? Are there any specific Health Canada regulatory safety requirements for “fashion face masks/covers”?**
  - There are no regulations *specific* to a fashion face covering or mask. However, it’s important to know that masks are assumed to be medical devices unless it is explicitly clear on the labelling that they are not intended for medical use. Additionally, the same regulations that would apply to any product being sold in Canada are still applicable and must be followed including:
    - It is prohibited to manufacture, import, advertise or sell any product that poses a “danger to human health or safety”, which is in accordance with paragraphs 7(a) and 8(a) of the Canada Consumer Product Safety Act (CCPSA). It is the responsibility of the retailer to ensure that face masks, including their components, do not pose a danger to human health or safety.
    - Like other apparel items, fashion face masks are required to meet other regulatory requirements, including (but not limited to):
      - Textile Flammability Regulations
      - Consumer Products Containing Lead Regulations
      - Surface Coating Materials Regulations
      - Phthalates Regulations
      - Consumer Packaging and Labelling Act and the Textile Labelling Act

- **If features are added to the mask such as a valve, filter, or wire around the nose would that change anything?**

Adding any extra features would not necessarily change the requirements. A retailer would still need to ensure the product is clearly labelled that it is not intended for medical use and not pose a danger to human health or safety.

- **As a retailer, would I need a Medical Device Establishment Licence (MDEL) to sell masks?**

A retailer would not require an MDEL to sell to the public. However, if they sell masks to a hospital or health care facility, they would be considered a medical device distributor and would require an MDEL.

