

Medical Devices including Personal Protective Equipment – COVID-19 FACT SHEET

Medical Devices (General):

1. What is a medical device ?
2. How do I know what class my device is (Classes I-IV)?
3. I make an App that takes your temperature, oxygen levels and heart rate. Am a medical device?
4. I am a current Medical Device Establishment Licence holder and I want to produce/import a medical device for use in relation to Covid-19. What approvals do I need from Health Canada?
5. I am a Canadian company that does not have a Medical Device Establishment Licence and I want to produce/import a medical device for use in relation to Covid-19. What approvals do I need from Health Canada?
6. How long does it take to get a Medical Device Establishment Licence?
7. How long will it take to get approval for my device from Health Canada?
8. Is there a list of products and specifications for the medical devices needed in relation to Covid-19 (e.g., ventilators)?
9. I would like to conduct a clinical trial for a medical device related to Covid-19. Who do I contact at Health Canada?
10. I have a medical device related to Covid-19. Does the Government have any supports for advancing this research?
11. I am a Canadian Company that wants to re-tool to produce medical devices for use in relation to Covid-19. Can I get funding to help switch over my business?
12. I am a manufacturer of a medical device for use in relation to Covid-19 and I have product I want to sell to the Government of Canada. Who should I talk to?
13. I am an organization looking to buy a medical device for use in relation to Covid-19. Where do I find approved devices?
14. Where can I find out which medical devices are currently being reviewed by Health Canada?

Personal Protective Equipment for Covid-19:

1. Is personal protective equipment considered a medical device?
2. Is there a list of products and specifications for the personal protective equipment needed in relation to Covid-19 (e.g., masks, gloves, gowns)?

Key Links:

Coronavirus – Canada's Response

Interim Orders

PSPC and ISED websites