

**Belliveau, Sébastien**

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**From:** MacKnight, Aisling (HC/SC) <aisling.macknight@canada.ca>  
**Sent:** May 12, 2020 6:52 AM  
**To:** Belliveau, Sébastien; Khalil, Samantha  
**Cc:** Gordon2, Travis (HC/SC)  
**Subject:** HC Approval stats - May 11  
**Attachments:** MDEL numbers May 11.docx

Morning both,

Sharing our latest figures on HC approvals under the interim order. Let us know if you have any questions.

Thanks,  
Ash

**Aisling MacKnight**  
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## HC APPROVALS: May 11

### MEDICAL DEVICES

As of **May 11**, Health Canada has authorized a **total of 148** medical devices under the *Interim order*:

- **17** test kits
- **134** non-diagnostic devices (non-IVDD devices):
  - **8** N95 masks
  - **39** surgical masks
  - **38** face shields
  - **4** ventilators
  - **9** gloves
  - **4** sterilizers
  - **32** Others (thermometers, airway management, beds, swabs, isolation kits, ventilator accessories, AI for diagnosis, test reagents, monitors, software, sterilizer solution, glucose monitoring, Spirometer, Bipap, CPAP helmets, infusion pumps and a thermal camera).
- Health Canada is **currently reviewing**:
  - **37** applications for **test kits**
  - **585** applications for **non-diagnostic devices**

As of **May 11**, Health Canada has authorized:

- **70** disinfectants
- **1,993** new hand sanitizer products
- and **1,436** new site licences for over-the-counter drugs and natural health products.

### INTERIM ORDER ON DRUG AND MEDICAL DEVICE SHORTAGES (imports):

- As of **May 8**, Health Canada has added **36 total medical devices** to the *List of Medical Devices for Exceptional Import and Sale* under the Interim Order.<sup>1</sup>
  - Ventilator: 1
  - Masks: 24
  - N95 respirator: 2
  - Gowns (including apron, sleeve, protective suit): 7
  - Face shield: 1
  - Gloves: 1
- As of **May 8**, Health Canada has added a **total of 27 drugs** to the *List of Drugs for Exceptional Import and Sale* under the Interim Order.<sup>2</sup>

### MEDICAL DEVICE ESTABLISHMENT LICENCES (MDELs)

- As of **May 8**, total MDELs issued under the interim order: **895**
- Total applications rejected based on lack of critical information required to ensure effective oversight of the activity being licensed: **193**
  - These companies receive an email indicating that the application was incomplete and have been provided with a link to guidance on how to apply.
- Total MDEL applications remaining in the queue: **40**

<sup>1</sup> Once added to the list, importers with medical device establishment licenses are permitted to import the products after notifying Health Canada 5 days in advance.

<sup>2</sup> Companies with a drug establishment license may import drugs on the *List of Drugs for Exceptional Import and Sale* after notifying Health Canada 5 days in advance of importation.