

## Belliveau, Sébastien

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**From:** MacKnight, Aisling (HC/SC) <aisling.macknight@canada.ca>  
**Sent:** May 5, 2020 8:01 PM  
**To:** Khalil, Samantha; Belliveau, Sébastien  
**Cc:** Gordon2, Travis (HC/SC); Exton, Adam (HC/SC)  
**Subject:** HC Approval numbers  
**Attachments:** MDEL numbers May 5 v2.docx

Hi,

New and updated info in the attached one-pager. Note that some of the info requested (region of MDEL) is unfortunately not able to be pulled because of how the applications are being processed by dept.

Let us know if you have questions.

Thanks,  
Ash

## HC APPROVALS: May 5

### MEDICAL DEVICES

As of **May 5**, Health Canada has authorized a **total of 137** medical devices under the *Interim order*:

- **17** test kits
- **120** non-diagnostic devices (non-IVDD devices):
  - **7** N95 masks
  - **38** surgical masks
  - **33** face shields
  - **4** ventilators
  - **6** gloves
  - **4** sterilizers
  - **28** 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).

As of **May 5**, Health Canada has authorized:

- **60** disinfectants and **1,799** hand sanitizers via a **Canadian** licence (DIN or NPN); and
- **338** products (including both disinfectants and hand sanitizers) under the Interim Order.\*

\*Products authorized under the interim order are all **imported** products that will not receive a license; it is not possible to easily separate imported and domestic products obtaining licences

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

- As of **May 5**, 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 5**, Health Canada has added a **total of 15 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 5**, total MDELs issued under the interim order: **831**
- Total applications rejected based on lack of critical information required to ensure effective oversight of the activity being licensed: **172**.
  - 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**
- MDEL amendments to be processed: 140

<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.