

Belliveau, Sébastien

From: MacKnight, Aisling (HC/SC) <aisling.macknight@canada.ca>
Sent: May 20, 2020 10:08 AM
To: Belliveau, Sébastien; Khalil, Samantha
Subject: HC approval numbers - May 20
Attachments: MDEL numbers May 20.docx

Hi folks,

Attaching the latest figures for QP today

Thanks,
Ash

HC APPROVALS: May 20

MEDICAL DEVICES

As of **May 19**, Health Canada has authorized a **total of 171** medical devices under the *Interim order*:

- **19** test kits
- **152** non-diagnostic devices (non-IVDD devices):
 - **8** N95 masks
 - **39** surgical masks
 - **43** face shields
 - **6** ventilators
 - **10** gloves
 - **4** sterilizers
 - **42** 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).

HAND SANITIZERS & DISINFECTANTS

As of **May 16**, Health Canada has authorized:

- **80** disinfectants
- **2,200** new hand sanitizer products
- **1,528** new site licences for over-the-counter drugs and natural health products.

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

- As of **May 19**, Health Canada has added **66 total medical devices** to the *List of Medical Devices for Exceptional Import and Sale* under the Interim Order.¹
 - Ventilator: 1
 - Masks: 41
 - N95 respirator: 3
 - Gowns (including apron, sleeve): 11
 - Protective suit/coverall: 4
 - Respirator filter: 1
 - Face shield: 2
 - Gloves: 3
- As of **May 19**, Health Canada has added a **total of 36 drugs** to the *List of Drugs for Exceptional Import and Sale* under the Interim Order.²

MEDICAL DEVICE ESTABLISHMENT LICENCES (MDELs)

- As of **May 20**, total MDELs issued under the interim order: **1,152**
- Total MDEL applications remaining in the queue: **30**

¹ 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.

² 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.