

Authorized medical devices for uses related to COVID-19: List of authorized medical devices other than testing devices

<u>Overview</u>	List of authorized testing devices	List of authorized medical devices other than testing
List of medical devices for expanded use	List of medical devices for exceptional import and sale	<u>List of products no longer authorized</u> under IO

This page is updated daily by 5:00 am EST.

If you recently learned that a device was authorized, please allow at least 48 hours for this list to be updated. Health Canada is receiving an extremely high volume of requests for authorization. We are unable to prioritize requests for status updates at this time.

In Canada, medical devices are classified into one of 4 classes. Class I represents the lowest risk and Class IV the highest. To determine the appropriate classification for their device, manufacturers are encouraged to refer to the classification rules for medical devices in the Medical Devices Regulations.

The following are examples of COVID-19 medical devices that fit within each class:

- Class I: masks, respirators, gowns, face shields
- Class II: infrared thermometers, gloves, personal protective equipment (PPE) decontamination devices, syringes
- Class III: ventilators
- Class IV: SARS-CoV-2 testing devices (see <u>list of authorized testing devices</u>)

We have authorized the following medical devices, other than testing devices, for sale or import in Canada. Authorization is through Interim Order No. 2 for importing and selling medical devices (enacted on March 1, 2021). Some devices were first authorized under Interim Order No. 1 for importing and selling medical devices (March 18, 2020, to March 1, 2021). Any medical device that was first authorized under Interim Order No. 1 is deemed as authorized under Interim Order No. 2.

Note that the number of entries appearing on this list represents the number of individual device identifiers included on each interim order authorization. For example, surgical face masks of different sizes are listed separately.

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IO authorization date 🕇 💺	IO authorization ID	Manufacturer	Device name	Device identifier	Device first issue date	Device type
2021-08-13	330763	Anhui Health Box Technology Co., Ltd. (China)	Disposable Medical Masks (foldable)	HB-118	2021- 08-13	PPE - Respirator

Date modified:

2021-03-05