

Spotlight on medical devices in the age of COVID-19

April 02, 2020

The global pandemic has created a need for medical devices including diagnostic tests, personal protective equipment, and ventilators. While these much-needed products are subject to regulatory oversight by Health Canada, the Canadian regulator has announced interim measures to facilitate expedited access to them.

We highlight some of the measures Health Canada has introduced through the federal [Minister of Health's Interim Order](#) of March 18, 2020 (the IO) and related communications, as well as some important considerations that manufacturers, importers and distributors should keep in mind in the coming months.

- **Expedited Access :** The IO allows for expedited authorization for the importation or sale of medical devices used in the diagnosis, treatment, mitigation, or prevention of COVID-19. Specifically, this mechanism allows the Minister to use her discretion to balance the benefits and risks of COVID-19 related devices and to fast-track authorizations where appropriate to meet the urgent public health need resulting from the pandemic. The IO provides a new application and authorization process for COVID-19 medical devices that a) are not yet licensed in Canada or elsewhere; b) are authorized by a trusted foreign regulatory authority; or c) are currently licensed under the Medical Devices Regulations for another purpose.
- **Application Approval Process:** Within the auspices of the IO, Health Canada has provided guidance on the required contents of an application for the authorization of importation or sale of COVID-19 medical devices. Health Canada has also outlined the labelling requirements for such devices. With respect to ventilators, **Health Canada has referred the industry to the US Federal Drug Administration's enforcement policy** to assist with informing application submissions to the Canadian regulator.
- **Relaxed Regulatory Requirements:** COVID-19 medical devices for which an IO authorization has been issued will also be exempted from most of the regulatory requirements set out in Part 1 of the Medical Devices Regulations. The IO, however, still mandates incident reporting and requires applicants to have **documented procedures for distribution record-keeping and recalls.**

While those wishing to import or sell Class I medical devices would typically require a Medical Device Establishment Licence (MDEL), it would no longer be required if Health

Canada issues an IO authorization because of an urgent public health need for the importation or sale of the device. Notably, however, for N95 respirators and other surgical, procedure and medical masks - which are considered Class I medical devices - Health Canada is endeavouring to complete the [MDEL approval process within 24 hours](#) of receiving a completed application from a company wishing to manufacture, import or distribute these products. Health Canada has also recently clarified that those wishing to manufacture Class I medical devices via 3D printing or other unconventional means for distribution or sale must hold either an IO authorization or a valid MDEL, subject to certain exceptions.

While the recent regulatory changes will assist in meeting the demand for COVID-19 medical devices, it is important to remember, despite the urgent need for such devices, regulatory requirements for approval must be carefully observed to ensure compliance and to mitigate the risks associated with any device-related issues down the road. Manufacturers, importers and distributors should avoid selling or otherwise transferring products that may be classified as medical devices before the necessary approvals are in place. Companies who have the capacity to manufacture or supply medical devices, but who do not have experience navigating the complex regulatory scheme for such devices, may wish to partner with companies who have an established history in the industry and/or engage legal counsel to ensure compliance. It is also important to keep abreast of new directions and guidance from Health Canada in this rapidly-evolving landscape.

BLG has created a [COVID-19 Resource Centre](#) to assist businesses on a variety of topics, including investment management, labour and employment, contractual risks, public disclosure requirements, education and criminal law.

By

[Glenn Zakaib](#), [Lydia Wakulowsky](#), [Keegan Boyd](#), [Edona C. Vila](#)

Expertise

[Health Regulatory](#), [Products Law](#), [Class Action Defence](#), [Health Care & Life Sciences](#), [MedTech](#)

BLG | Canada's Law Firm

As the largest, truly full-service Canadian law firm, Borden Ladner Gervais LLP (BLG) delivers practical legal advice for domestic and international clients across more practices and industries than any Canadian firm. With over 800 lawyers, intellectual property agents and other professionals, BLG serves the legal needs of businesses and institutions across Canada and beyond – from M&A and capital markets, to disputes, financing, and trademark & patent registration.

blg.com

BLG Offices**Calgary**

Centennial Place, East Tower
520 3rd Avenue S.W.
Calgary, AB, Canada
T2P 0R3

T 403.232.9500
F 403.266.1395

Ottawa

World Exchange Plaza
100 Queen Street
Ottawa, ON, Canada
K1P 1J9

T 613.237.5160
F 613.230.8842

Vancouver

1200 Waterfront Centre
200 Burrard Street
Vancouver, BC, Canada
V7X 1T2

T 604.687.5744
F 604.687.1415

Montréal

1000 De La Gauchetière Street West
Suite 900
Montréal, QC, Canada
H3B 5H4

T 514.954.2555
F 514.879.9015

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3

T 416.367.6000
F 416.367.6749

The information contained herein is of a general nature and is not intended to constitute legal advice, a complete statement of the law, or an opinion on any subject. No one should act upon it or refrain from acting without a thorough examination of the law after the facts of a specific situation are considered. You are urged to consult your legal adviser in cases of specific questions or concerns. BLG does not warrant or guarantee the accuracy, currency or completeness of this publication. No part of this publication may be reproduced without prior written permission of Borden Ladner Gervais LLP. If this publication was sent to you by BLG and you do not wish to receive further publications from BLG, you may ask to remove your contact information from our mailing lists by emailing unsubscribe@blg.com or manage your subscription preferences at blg.com/MyPreferences. If you feel you have received this message in error please contact communications@blg.com. BLG's privacy policy for publications may be found at blg.com/en/privacy.

© 2026 Borden Ladner Gervais LLP. Borden Ladner Gervais LLP is an Ontario Limited Liability Partnership.