3D printing during COVID-19

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COVID-19 has led to extraordinary demand for medical equipment and supplies. Global supply chain interruptions means the need for certain medical devices, including personal protective equipment (PPE), outpaces the available supply. To respond to this demand, organizations are using 3D printing and other innovative manufacturing processes to produce urgently required medical devices, including PPE and ventilator parts. 3D printing is an additive manufacturing approach where successive layers of raw material are printed and piled until a solid 3D object is formed.

As part of Health Canada's response to the pandemic, the regulator has released guidance on 3D printing and manufacturing PPE. Below we highlight the Canadian regulator's approach, as well as important considerations for manufacturers, importers and distributors of COVID-19 related medical devices.

Class I medical devices: The majority of PPE, including face shields, N95 respirators and other surgical, procedure, and medical masks, are considered Class I medical devices. Health Canada has clarified that anyone wishing to manufacture or distribute a Class I medical device made by 3D printing or other innovative means, must either hold an authorization under the Interim Order (IO) respecting the importation and sale of medical devices for use in relation to COVID-19 or a valid Medical Device Establishment License (MDEL), subject to certain exceptions.

The IO allows for expedited authorization for importing or selling medical devices used in diagnosing, treating, mitigating, or preventing COVID-19. Specifically, this mechanism 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.

Health Canada has committed to reviewing all applications under the IO as quickly as possible. The regulator is also fast tracking MDEL applications for organizations wishing to manufacture, import, or distribute Class I medical devices.

***Class II medical devices and above*:** 3D printing and other innovative manufacturing techniques may evolve to include COVID-19 related medical devices considered Class II and above, such as medical exam gloves, oxygen masks, and other medical device accessories, components, and parts. Health Canada has committed to expediting authorizations relating to these products under the IO and to fast tracking MDEL applications.

Relaxed standards in urgent manufacturing scenarios: Improvised production may occur if the demand for PPE, including face shields, outpaces supply. If urgent production of PPE is required, IOs and MDELs will still be required. Health Canada will, however, relax regulatory standards and only require that certain minimum specifications be incorporated into the design and verification of PPE to maintain their safety.

Health Canada is also encouraging stakeholders to reference the U.S. Federal Drug Administration's (U.S. FDA) guidance to assist with informing their application submissions to the Canadian regulator. Recently, the U.S. FDA released guidance on 3D printing medical devices during COVID-19.

In this guidance, the U.S. regulator acknowledges that 3D printing may increase access to urgently needed devices. The U.S. FDA also cautions that some devices are more amenable to printing than others, and that technical barriers will need to be overcome. Given the fast-changing regulatory landscape for medical devices, supply chain stakeholders must observe regulatory compliance and consider mitigating as against liability risks that may materialize at the end of this pandemic.

For assistance in the myriad considerations involved in 3D printing and manufacturing PPE, our team listed below is ready and available to assist. BLG has also 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.

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