

CERTIFICATION Informs

An Urgent Bulletin from CSA Group

Ref No: I20-108

Occupational Health and Safety Products No. 133

Date: October 19, 2020

New Service available as of today

Apply any time to have your products evaluated

Announcing: New CSA Certification Program for Medical Face Masks
(See Attachment 1 for standards and requirements)

Class No.: 7203 01 Occupational Health and Safety Products – Medical Face Masks

Who is affected?

Manufacturers of medical face masks.

What do you do?

1. This publication provides for new certification services.
2. Please contact CSA technical staff if you have questions or need information concerning this publication and how it applies to you.
3. If you would like to take advantage of the new certification services, initiate a certification project by contacting our Client Services Centre at 1-866-797-4272. Please supply appropriate supporting documentation* and we will inform you of the samples required.

*which includes technical information, company name, address, factory locations and CSA file number or master contract number (if assigned), and any other relevant documentation.

Introduction:

In Canada, there is currently no domestic provider of comprehensive testing, inspection and certification services of medical grade masks, gloves, protective drapes and gowns. On March 18, 2020, Canada's Minister of Health issued an Interim Order with respect to the importation and sale of medical devices for use in relation to the COVID-19 pandemic. To assist manufacturers in meeting the Health Canada Interim Order requirements, CSA has established a new certification program with an accredited, special-purpose lab, dedicated to the testing and certification of medical face masks that are used in providing healthcare services such as surgery and patient care.

Certified products will be listed under class number 7203 01 OCCUPATIONAL HEALTH AND SAFETY PRODUCTS – Medical Face Masks.

Background and Rationale:

See Attachment 1

For questions specific to your file or products contact your CSA Group technical staff associate.

Go to <https://www.csagroup.org/testing-certification/product-listing/> and enter your Master Contract # and the class numbers associated with this Informs to view your certified products.

For technical questions on this Informs

Contact Sally Guo
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Visit us at www.csagroup.org where you can click on "Contact Us" for the online phone listing of our Offices and Partners.

ATTACHMENT 1

Background and Rationale

This program covers the construction and barrier performance of medical face masks that are used in providing healthcare services such as surgery and patient care. The material performance is based on testing in accordance with the requirements of ASTM F2100 for resistance to penetration by synthetic blood, bacterial filtration efficiency (BFE), breathability, sub-micron particulate filtration efficiency (PFE), Breathability/Differential pressure and flammability.

Level 1 barrier medical face mask materials are evaluated for their ability to capture sub-micron particles, resistance to penetration by synthetic blood at the minimum velocity specified in ASTM F1862, bacterial filtration efficiency, and differential pressure.

Level 2 barrier medical face mask materials are evaluated for their ability to capture sub-micron particles and are evaluated for resistance to penetration by synthetic blood at the middle velocity specified in ASTM F1862, bacterial filtration efficiency, and differential pressure.

Level 3 barrier medical face mask materials are evaluated for resistance to penetration by synthetic blood at the maximum velocity specified in ASTM F1862, submicron particulate filtration, bacterial filtration efficiency, and differential pressure.

NOTE:

1. This program does not cover biocompatibility testing. It is the responsibility of the manufacturer to source materials that have already been tested to skin sensitization, cytotoxicity and hypersensitivity in accordance with ISO 10993-5, ISO 10993-10.
2. The program does not evaluate medical face masks for regulatory approval as respirators. It specifically only evaluates the construction and barrier performance of the medical face mask and not the seal of the medical face mask against the wearer's face or other design features that determine its effectiveness of preventing the particle or liquid exposure to the wearer. If respiratory protection for the wearer is needed, a respirator meeting the requirements of 42 CFR 84 shall be used, see Class 7204 01.
3. In addition to ASTM F2100, this program involves additional construction requirements for certification.