Ref No: I20-111

Occupational Health and Safety Products No. 136

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 Gloves
(See Attachment 1 for standards)

Class No.: 7205 01 Occupational Health and Safety Products – Medical Gloves

Who is affected?
Manufacturers of medical gloves intended for use in healthcare facilities.

What do you do?
This publication provides for new certification services.

1. Please contact CSA technical staff if you have questions or need information concerning this publication and how it applies to you.

2. 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.

3. *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, respirators, 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 COVID-19. 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 gloves intended for use in healthcare facilities.

Certified products will be listed under class number 7205 01 OCCUPATIONAL HEALTH AND SAFETY PRODUCTS – Medical Gloves.

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
by phone 416-747-2348, fax 416-747-4149
or e-mail sally.guo@csagroup.org

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 disposable gloves used in conducting medical examination, diagnostic and therapeutic procedures as well as general patient care. Gloves are evaluated for physical properties, dimensions, freedom from holes and residual powder.

Medical gloves are evaluated in accordance with the following standards as applicable, depending on the type of material:

ASTM D6319 - Standard Specification for Nitrile Examination Gloves for Medical Application

ASTM D3578 - Standard Specification for Rubber Examination Gloves

ASTM D5250 - Standard Specification for Poly(vinyl chloride) Gloves for Medical Application

ASTM D6977 - Standard Specification for Polychloroprene Examination Gloves for Medical Application

NOTE: This program involves additional requirements for CSA Certification.