Ref No: I20-106

Occupational Health and Safety Products No. 131

Date: October 19, 2020

Announcing: New CSA Certification Program for Protective Apparel
(See Attachment 1 for standards and requirements)

Class No.: 7202 01 Occupational Health and Safety Products – Protective Apparel Intended for Use in Healthcare Facilities

Who is affected?
Manufacturers of protective apparel such as surgical gowns, isolation gowns.

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.

*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, 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 surgical gowns, isolation gowns and other protective apparel intended for use in healthcare facilities.

Certified products will be listed under class number 7202 01 OCCUPATIONAL HEALTH AND SAFETY PRODUCTS – Protective Apparel Intended For Use in Healthcare Facilities.

Background and Rationale:
See Attachment 1

For technical questions on this Informs
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ATTACHMENT 1

Background and Rationale

Four levels of barrier properties for surgical gowns are specified in AAMI PB70 – Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.

The critical zones of surgical gowns, isolation gowns, other protective apparel, shall be classified as defined below:

Level 1: When tested for water resistance in accordance with AATCC 42 (impact penetration) and under the conditions specified in ANSI/AAMI PB70, all critical zone components shall have a blotter weight gain of no more than 4.5 grams (g).

Level 2: When tested for water resistance in accordance with AATCC 42 (impact penetration) and AATCC 127 (hydrostatic pressure) and under the conditions specified in ANSI/AAMI PB70, all critical zone components shall have a blotter weight gain of no more than 1.0 g and a hydrostatic resistance of at least 20 cm.

Level 3: When tested for water resistance in accordance with AATCC 42 (impact penetration) and AATCC 127 (hydrostatic pressure) and under the conditions specified in ANSI/AAMI PB70, all critical zone components shall have a blotter weight gain of no more than 1.0 g and a hydrostatic resistance of at least 50 cm.

Level 4: When a surgical gown, isolation gown or other item of protective apparel is tested for resistance to bacteriophage Phi-X174 in accordance with ASTM F1671 and under the conditions specified in ANSI/AAMI PB70, all critical zone components shall demonstrate passing results.

Note: This program involves additional requirements for CSA certification.