

# CERTIFICATION Informs

An Urgent Bulletin from CSA Group

Ref No: I20-110

Occupational Health and Safety Products No. 135

New Service available as of today

Date: October 19, 2020

Apply any time to have your products evaluated

Announcing: New CSA Certification Program for Medical Filtering Facepiece Respirators (FFR)  
(See Attachment 1 for standards and requirements)

Class No.: 7204 02 Occupational Health and Safety Products – Medical Non-Powered Air-Purifying Filtering Facepiece Respirators

## Who is affected?

Manufacturers of medical non-powered air-purifying filtering facepiece respirators.

## 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, 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 the COVID-19 pandemic. And on August 25, 2020, Health Canada published the *Safety and performance specifications for respirators during COVID-19: Guidance for Canadian manufacturers*. 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 use filtering facepiece respirators (FFRs) that cover the user's airway (nose and mouth) and offer protection from particulate materials at specified filtration efficiency.

Certified products will be listed under class number 7204 02 OCCUPATIONAL HEALTH AND SAFETY PRODUCTS – Medical Non-Powered Air-Purifying Filtering Facepiece Respirators.

## 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](mailto:sally.guo@csagroup.org)



Visit us at [www.csagroup.org](http://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**

Medical Filtering Facepiece Respirators shall be tested in accordance with the requirements in The Code of Federal Regulation 42 CFR Part 84, Approval of Respiratory Protective Devices, Subpart G (General Construction and Performance Requirements) and K (Nonpowered Particulate Respirators); and the Health Canada Interim Order Guidance for:

- Particulate Filtration Efficiency;
- Mechanical strength of head strap or head harness;
- Fluid resistance;
- Exhalation/inhalation resistance; and
- Exhalation valve leakage testing (only for reusable respirators with an exhalation valve).

This program also includes reusable elastomeric half-facepiece respirators with replaceable filters, cartridges or canisters and have tight-fitting facepieces made of polymeric material which can be repeatedly cleaned, disinfected and reused.

Respirators that meet the 95% particulate filter efficiency level shall be labelled "95PFE-L#" – the "#" represents the ASTM F1862 fluid resistance level 1, 2 or 3 whichever is the highest level obtained by the product;

Respirators that meet the 99% particulate filter efficiency level shall be labelled "99PFE-L#" - the "#" represents the ASTM F1862 fluid resistance level 1, 2 or 3 whichever is the highest level obtained by the product;

Respirators that meet the 99.97% particulate filter efficiency level shall be labelled "100PFE-L#" - the "#" represents the ASTM F1862 fluid resistance level 1, 2 or 3 whichever is the highest level obtained by the product.

NOTE: This program involves additional requirements for CSA certification.



# Certificate of Compliance

**Certificate:** 80075242

**Master Contract:** 301795

**Project:** 80075242

**Date Issued:** 2021-05-28

**Issued To:** Eclipse Innovations Inc.  
130 Thompson Drive  
Cambridge, Ontario, N1T 2E5  
Canada

**Attention:** Gagandeep Arora

*The products listed below are eligible to bear the CSA Mark shown*

**Issued by:** Wendy Zhu  
Wendy Zhu, Ph. D., P. Eng.



## **PRODUCTS**

CLASS - C720402 - OCCUPATIONAL HEALTH & SAFETY Surgical Non-Powered Air-Purifying Respirators

Surgical Respirator Model HORIZON (sizes small, regular, large) and ARC (sizes regular and large), single-use and disposable, 95PFE-L3

## **APPLICABLE REQUIREMENTS**

- The Code of Federal Regulation 42 CFR Part 84, Approval of Respiratory Protective Devices, Subpart K (Nonpowered Particulate Respirators).
- The Code of Federal Regulations, Title 16- Commercial Practices, Part 1610, Standard for the Flammability of Clothing Textiles
- ASTM F1862-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood
- CSA TechNote TN202, Filtering Facepiece Respirator Head Strap / Harness Assembly Strength Requirements and Test Procedure



## *Supplement to Certificate of Compliance*

**Certificate:** 80075242

**Master Contract:** 301795

*The products listed, including the latest revision described below,  
are eligible to be marked in accordance with the referenced Certificate.*

### **Product Certification History**

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<b>Project</b>	<b>Date</b>	<b>Description</b>
80075242	2021-05-28	Original certification of Surgical Respirator models HORIZON (sizes small, regular, large) and ARC (sizes regular and large) 95PFE - L3 single-use and disposable. The Code of Federal Regulation 42 CFR Part 84, Subpart K The Code of Federal Regulations, Title 16- Commercial Practices ASTM F1862-17 CSA TechNote TN202