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December 17th, 2021

To: Supply Chain Professionals

Subject: Eclipse Innovations Surgical Respirators and Procedure Masks

Thank you for your interest in the medical PPE offered by Eclipse Innovations Inc. Our Made-In-Ontario procedure masks and respirators have been designed and tested to meet the rigors of healthcare and frontline use. This letter is intended to provide supporting information and assurance to the high-quality of our medical PPE products.

Certification

The Health Canada Interim Order (IO) set up by the Minister of Health, establishes measures for drugs, medical devices and dietary food required to address shortages relating to the COVID-19 pandemic in accordance with the subsection 30.1(1) of the Food and Drugs Act.
The Interim Order:

1. ***Expedites*** authorization for the sale or import of Medical Devices (Class I to IV), drugs and special dietary food considered critical during COVID-19 pandemic.
2. ***Expedites*** authorization of Biocide Drugs (such as hard disinfectant, hand sanitizers) considered critical during COVID-19 pandemic.
3. Introduces requirements for medical device manufacturers to notify Health Canada on the shortages of critical medical devices during COVID-19 pandemic.

To manufacture, sell, or import Class I medical devices for human use in Canada, Eclipse Innovation Inc. applied and received a Medical Device Establishment License (MDEL) issued by Health Canada's Regulatory Operations and Enforcement Branch (ROEB). The MDEL allowed Eclipse Innovations Inc. to manufacture and sell N95 equivalent surgical respirators which are Class I medical devices.

Furthermore, with the establishment of the *Interim Order (IO)*, Health Canada along with the Public Health Agency of Canada (PHAC) and National Research Council (NRC), supported by the Canadian Standards Association (CSA) set requirements for the development and testing of N95 and equivalent respirators in March 2020.

Health Canada Interim Order No. 1 was introduced in March 2020 and was valid for one year which further transitioned into Interim Order No. 2, being valid until the fall of 2021. As a part of the Interim Order authorization process, Health Canada announced that the manufacturers of filtering facepiece respirators (FFRs) must certify their products using the new CSA Group's medical PPE certification program launched in October, 2020 which is based on NIOSH requirements and promotes a similar level of quality standards in its certification program.

Eclipse Innovations Inc. manufactures two types of approved surgical respirators with the trade-name ARC and HORIZON and a third line of medical procedure masks with the trade-name OMNIA. Both the ARC and HORIZON surgical respirators meet the following requirements:

- Code of Federal Regulation 42 CFR Part 84, Approval of Respiratory Protective Devices, Subpart G (General Construction and Performance Requirements)
- Subpart K (Nonpowered Particulate Respirators)
- Health Canada Interim Order Guidance
- CLASS - C720402 - OCCUPATIONAL HEALTH & SAFETY Surgical Non-Powered Air-Purifying Respirators

The OMNIA procedure masks meet the ASTM F2100 - Standard Specification for Performance of Materials used in Medical Face Masks.

Performance Criteria

To meet the performance criteria for surgical respirators and procedure masks, Eclipse Innovations Inc. utilized PHAC, NRC, Kinectrics Inc., Chalk River Laboratories, Nucro-Technics Inc., NAMSA and Nelson Labs as the testing bodies to assess Facepiece Filtering Respirator (FFR) performance for particulate filter efficiency, mechanical strength of headstrap, breathing resistance, flammability and fluid resistance.
Test samples submitted were not prototypes but regular production items from the actual manufacturing process. The tests performed are in accordance with the performance criteria and test standards specified by Health Canada and CSA as described in the Table 1 & 2. The test standards specified are similar to the approval criteria and standards specified by NIOSH. The fit test for our ARC/HORIZON surgical respirators

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was performed by Eclipse Innovations with the help of a TSI PortaCount tester in accordance with CSA Z94.4-18 on a total of 10 subjects. This mirrors NIOSH face panels identified in RCT-APR-STP-0005-05a-06, revision 3.0.

The Biocompatibility tests including Cytotoxicity, Dermal Irritation and Skin Sensitization for a complete respirator was performed at NAMSA, a Medical Device Testing & Clinical Research lab in Northwood, Ohio. The tests are performed in accordance with ISO-10993-1 standard, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process." and this standard is accepted by Health Canada, CSA and NIOSH.

Test	Health Canada/ CSA	NIOSH	Testing Body	Results
Particulate Filter efficiency	NIOSH 42 CFR 84 (TEB-APR-STP-0059) ≥95%	NIOSH 42 CFR 84 (TEB-APR-STP-0059) ≥95%	Kinectrics Inc. + NRC	Avg. Filtration Efficiency - 99%
Breathing resistance	42 CFR 84.180 Inhalation < 35 mmH2O Exhalation < 25 mmH2O	42 CFR 84.180 Inhalation < 35 mmH2O Exhalation < 25 mmH2O	Kinectrics Inc. + NRC	Pass - Inhalation Resistance - 15.6mm H2O Exhalation Resistance - 13.3mm H2O
Mechanical strength of Headstrap	Ability to withstand a 10 N (0.98) kg weight force for 10 seconds for each headstrap tested	Not Applicable	PHAC	Pass
Fit (each size)	CAN/CSA Z94.4 Testing done in accordance with NIOSH face panels identified in RCT-APR-STP-0005-05a-06, revision 3.0	Not Applicable	Eclipse Innovation Inc.	100% of the subjects passed the fit test with at least one size of mask.
Flammability	16 CFR Part 1610	16 CFR Part 1610	Nelson Labs	Pass - Class 1: Burn time≥3.5s
Fluid Resistance	ASTM F1862 - Standard test method for resistance of surgical mask to penetration by synthetic blood	ASTM F1862 - Standard test method for resistance of surgical mask to penetration by synthetic blood	Nelson Labs	Pass - 160 mmHg - ASTM Level 3
Biocompatibility	ISO-10993-1 standard, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process	ISO-10993-1 standard, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process	NAMSA	Passed the Cytotoxicity, Skin Sensitization and Dermal Irritation Test

Table 1: Test Results for Surgical respirators (ARC/HORIZON)

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Test	Standard	Testing Body	Results
Particulate Filtration Efficiency	ASTM F2299	Kinectrics Inc.	Avg. Filtration Efficiency - 99.77%
Differential Pressure	EN 14683 Annex C	Kinectrics Inc.	Avg. Differential Pressure -2.98 H2O/cm2
Flammability	16 CFR Part 1610	Kinectrics Inc.	Passed - Class 1: Burn time≥3.5s
Fluid resistance to Synthetic Blood	ASTM F1862 - Standard test method for resistance of surgical mask to penetration by synthetic blood	Kinectrics Inc.	Passed at 160 mmHg - ASTM Level 3
Bacterial Filtration Efficiency	ASTM F2101	Kinectrics Inc.	Avg. Filtration Efficiency - 99.952%
Biocompatibility (each patient skin contacting component)	ISO-10993-1 standard, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process	Charles River Laboratories Hungary Kft. + Nucro-Technics Inc.	Pass the Cytotoxicity, Skin Sensitization and Dermal Irritation Test

Table 2: Test Results for Procedure Masks (OMNIA)

Conclusion

Test results demonstrate that Eclipse Innovations respirators have surpassed the approval criteria specified by Health Canada and CSA and also meet or exceed the performance criteria and testing standards specified by NIOSH. The Health Canada Interim Order authorization certifications for both ARC (HC IO# 320544) and HORIZON (HC IO# 321423) surgical respirators were granted in September 2020 and November 2020 respectively. Eclipse Innovations also received the Certificate of Compliance (Certification# 80075242) for the initial CSA medical PPE Certification program for Filtering Facepiece Respirator (FFRs). Eclipse Innovations is approved by CSA to perform factory testing of our products on our TSI 8130A Automated Filter Tester, utilizing trained and certified operators to conduct the testing.

Further, our procedure mask has passed the performance requirements as specified in ASTM F2100 - Standard Specification for Performance of Materials used in Medical Face Masks.

Submission for NIOSH approval is underway for both ARC and HORIZON surgical respirators. We are anticipating approval for both respirators in February 2022. Should you have any further questions about the content herein, please contact our knowledgeable personnel through our website.

Sincerely,

Rob Shwery

General Manager