15 June 2020

Health Canada
Health Products and Food Branch
Medical Devices Directorate

Approval of the CAEAir1 ventilator IO application

CAE

- CAE is a global leader in training for the civil aviation, defence and security, and healthcare markets, and the company is located in Montreal, QC.
- CAE currently holds 2 Interim Order Authorizations (IOA) in Canada (1 conditional approval)
    - Battelle Critical Care Decontamination System, Class II, IOA issued on 2020-05-22
    - CAE Reprocessed N95 Respirators, Class II, conditional IOA issued on 2020-05-27
- CAE is part of ISED's Made in Canada ventilator project, and is currently under contract with the Government of Canada to deliver 10,000 ventilators by the Fall 2020 to help with COVID-19.

The CAEAir1 Ventilator

- CAEAir1 ventilator is new and has not been approved in any jurisdiction to date.
- This ventilator is manufactured in Montreal, QC.
- CAE was quoted on this initiative in this Financial Post article.
- The CAEAir1 ventilator is designed for continuous invasive ventilation for adult patients.
- The ventilator utilizes gas supply from room air and a pressurized oxygen source.
- The ventilator comprises air-mixing and pressure output features that are managed electronically and controlled by dedicated software.
- The ventilator supports three modes of mechanical ventilation: Pressure-Control, Volume-Control and Pressure Support.
- Health Canada has determined that the CAEAir1 ventilator meets the safety and effectiveness requirements to be eligible for authorization under the Interim Order for medical devices.
- CAE plans to seek approval of their ventilator in other jurisdictions following Health Canada approval.

Its intended use

- The CAEAir1 is a continuous ventilator for invasive applications with pressure control, volume control and pressure support modes, with the provision of an adjustable percentage of oxygen in the breathing gas.
- The CAEAir1 is indicated for use on adult patients in healthcare facilities, and under the supervision of trained healthcare providers.

Next steps

- Health Canada will authorize the application on June 16, 2020
- This information will be posted the same day on the List of authorized devices for COVID-19 other than testing devices.
- Anticipatory reactive media lines and this one-pager have been prepared.
- Minister Bains may announce this authorization in his PPE weekly update. This update will most likely take place on Wednesday (June 17).

Approved by
David Boudreau
Director General
Medical Devices Directorate