Before completing this form, you must consult the *DRAFT – Guidance Document Applications for Medical Devices under the Interim Order for Use in Relation to COVID-19*).

1. **NAME OF THE DEVICE** (as it appears on the label)

Aerosol-Reducing Mask for use with BiPAP and CPAP machines

2. **MANUFACTURER INFORMATION** (as it appears on the label)

Contact Name and Title: Dr. Tarek Loubani, President and Medical Director		Company ID (if known): 141507	
Company Name: Glia Inc.			
Telephone: (519) 488-6475	Fax:	E-mail: tarek@tarek.org	
Street: 54 Craig Street		Suite:	P.O. Box:
City: London	Province/State: ON	Country: Canada	Postal/Zip Code: N6C 1E8

3. **ADDRESS OF MANUFACTURING SITE (If different from Manufacturer)** ☒ Same as Manufacturer ☐ Other (specify below)

Company Name:		Company ID (if known):	
Street:		Suite:	P.O. Box:
City:	Province/State:	Country:	Postal/Zip Code:

4. **REGULATORY CORRESPONDENT INFORMATION** ☒ Same as Manufacturer ☐ Other (specify below)

Contact Name and Title:		Company ID (if known):	
Company Name:			
Telephone:	Fax:	E-mail:	
Street:		Suite:	P.O. Box:
City:	Province/State:	Country:	Postal/Zip Code:

5. ATTESTATION

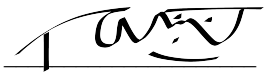
Under 4(1)(i) of the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID*-19, an applicant is required to attest to the availability of documented procedures for certain activities.

I, **the Applicant**, have objective evidence to establish that I have documented procedures in place with respect to distribution records, complaint handling, incident reporting and recalls. I submit this attestation in partial fulfillment of the application submission requirements of the **Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.**

I, as a senior official of the manufacturer of this application, hereby attest that I have direct knowledge of the item checked above and declare that these identified statements are true and that the information provided in this application and in any attached documentation is accurate and complete.

Where a person is named in Section 5 of this application, I hereby authorize that person to submit this application to the Minister on my behalf. I further authorize the Medical Devices Directorate to direct all correspondence relating to this application to the person named in Section 5 of this application.

Name: Tarek Loubani
Title: President and Medical Director

Signature: 
Date: 2020 April 17

6. **PURPOSE/INTENDED USE OF DEVICE** (A description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented as per the device labelling.)

The intended purpose of the aerosol-reducing mask (also known as the MAIN-Covid19 mask) is to allow the use of non-invasive positive pressure ventilation (NIPPV) machines for patients that have COVID-19, or similar symptoms, by reducing aerosolization. It is intended for use in emergency rooms, intensive care units, prehospital transport, intra- and inter-hospital transport, and remote nursing stations.

A major challenge associated with COVID-19 is the demand it places on the use of invasive ventilators. Traditional non-invasive ventilation strategies, such as Continuous Positive Airway Pressure (CPAP) and Bi-level Positive Airway Pressure (BiPAP) vent directly to the atmosphere due to masks that are not fully sealed. Therefore, practitioners are reluctant to use non-invasive ventilation due to the increased risk of spreading coronavirus to healthcare providers and patients. The MAIN-Covid mask can be used to provide fully functional CPAP or BiPAP ventilation while decreasing the level of aerosolization, thus reducing the risk of infection to others. It will have the added benefit of reducing the strain on existing supplies of fully invasive ventilation machines.

7. **IDENTIFIER OF DEVICE** (include an identifier for each device or medical device group listed, adding additional rows as necessary)

Name of device, components, parts and/or accessories as per product label	Identifier for device (bar code, catalogue, model or part number)	Device Risk Class (if known)	GMDN (if known)	Preferred Name Code (if known)
Aerosol-reducing mask for use with BiPAP and CPAP machines	Model #: 004	NA	NA	

8. AVAILABILITY OF DEVICE

Quantity Available for Immediate Shipment: 1000
Approximate Shipment Date: 17 April 2020
Ongoing Availability: 10,000 units per month, with the potential to scale up to 50,000 units per month.

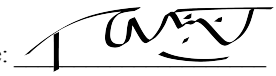
9. DISCLOSURE REQUEST

As the COVID-19 pandemic situation is evolving, Health Canada would like to ensure that the most up-to-date information related to available technologies for use in the diagnosis, treatment, mitigation and prevention of COVID-19 is publicly available. To that effect, Health Canada would like to make available on our website a statement indicating that your company has submitted a request for authorization under our Interim Order, and the expected device availability and timelines for Canadian acquisitions. Please select one of the following:

■ This certifies that **the manufacturer** *(listed in Section 2 above)* has **no objection** to the disclosure and/or publishing of the receipt of this application, for the device(s) listed above, by the Medical Devices Directorate.

☐ This certifies that **the manufacturer** *(listed in Section 2 above)* **objects** to the disclosure and/or publishing of the receipt of this application, for the device(s) listed above, by the Medical Devices Directorate.

Name: Tarek Loubani
Title: President and Medical Director

Signature: 
Date: 2020 April 17