03- Application Form

APPLICATION FOR INVESTIGATIONAL TESTING AUTHORIZATION
(*disponible en francais*)

1. DEVICE CLASSIFICATION

☑ Class II □ Class III □ Class IV

1. DEVICE NAME (as it appears on label)
[Note: this is the device name for which the Authorization will be issued]

Pulse oximeter

2. PROTOCOL IDENTIFICATION:
Include the type of diagnosis or treatment for which the device will be sold.

The purpose of this device is to non-invasively measure oxyhemoglobin and deoxyhemoglobin, presenting clinicians and users with an oxygen saturation (SpO2), which is an estimate of partial pressure of oxygen in the bloodstream (pO2). The device is a monitoring device and has no specific therapeutic use.

3. NAME AND ADDRESS OF MANUFACTURER (as it appears on the label)
[Note: this is the name and address to which the Authorization will be issued]

Company Name	Glia Inc.	
Street Address/P.O. Box: 54 Craig St. City: London Province/State: Ontario Postal/Zip Code: N6C 1E8 Country: Canada		
Contact Name and Title:	Dr. Tarek Loubani, Primary investigator and Emergency Physician	
Telephone No.**:** **+1 519 488 6475**		Fax No.**: NA**
E-Mail Address:	tarek@tarek.org	

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4. MAILING ADDRESS FOR REGULATORY CORRESPONDENCE (if different from 4)

Note: (i) The Authorization will be **issued** to Company named in Item 4 but will be **sent** to the Company shown below if different. (ii) The Company named below must be authorized by the manufacturer named in Item 4 to submit an authorization application on their behalf.

Company Name		
Street Address/P.O. Box City Province/State Postal/Zip Code Country		
Contact Name and Title:		
Telephone No.**:**	Fax No.**:**	
E-Mail Address:		

5. DEVICE TYPE (check one only)

Single Device	✓
Medical Device Group	
Medical Device Family	
Medical Device Group Family	
Test Kit	
System	

6. PREFERRED NAME CODE: (xxAAA) optional

7. IS THIS DEVICE A NEAR PATIENT *IN VITRO* DIAGNOSTIC (IVDD)?

Yes☐ No☒

IS THIS DEVICE INTENDED TO BE SOLD FOR HOME USE? Yes☐ No☒

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8. DEVICE USAGE CATEGORY

(73) Anaesthesiology	✓	(84) Neurology	
(74) Cardiovascular	✓	(85) Obstetrics & Gynaecology	
(76) Dental		(86) Ophthalmology	
(77) Ear, Nose & Throat		(87) Orthopaedics	
(78) Gastroenterology & Urology		(89) Physical Medicine	
(79) General & Plastic Surgery		(90) Radiology/Imaging	
(80) General Hospital	✓		

FOR IVDDs ONLY

(75) Chemistry		(83) Microbiology	
(81) Haematology		(88) Pathology	
(82) Immunology		(91) Clinical Toxicology	

9. DOES THIS DEVICE CONTAIN A DRUG? Yes☐ No☒
(Note: this question does not apply to IVDDs)

If yes

Brand /Trade Name of Drug:
Active Ingredient:
Drug Manufacturer:
Applicable Drug Identification Number (if any):

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10. DEVICE DETAIL

Please provide the following information, where applicable for each component device, part or accessory.

Name of Device, Components, Parts and/or Accessories as per product label	Device Identification Number if previously assigned	Model or Catalogue number
Pulse Oximeter – control unit	None assigned	POX-C001
Pulse Oximeter – finger probe	None assigned	POX-F001

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11. ATTACHMENTS

In addition to items 1 to 11, of the Application for investigational testing, please indicate (🔊) which of the relevant information requirements listed below, are included as attachments to this application, or will be provided at a later date. For details regarding content and format, please refer to the guidance documents "Preparation of an Application for Investigational Testing - Medical Devices" and "Preparation of an Application for Investigational Testing - in Vitro Diagnostic Devices"

	Attached	To Come
Background Information	x	
Risk Assessment	NA	
Ethics Committee or IRB Approval(s)	x	
Protocol	x	
Device Label	x	
Investigator Agreements	x	

12. If this Device contains a drug and it does **not** have a Drug Identification Number, **I the Manufacturer of this device attest** that the (☐ **drug meets**) (☐ **drug does not meet**) acceptable standards of safety, efficacy and quality.

I hereby certify that the information provided on this application and in any attached documentation is correct, complete and in accordance with all relevant sections of the *Medical Devices Regulations*.

Name of Signing Official: Tarek Loubani

Signed:  **Date:** 2018 August 8