Health Canada Santé Canada

Medical Devices - Inspection Programme
Instruments médicaux - Programme d'inspection

Inspection Report / Rapport d'inspection

Draft / Ebauche
2019-11-07

Company Inspected / Compagnie inspectée

Glia Inc.
54 Craig Street
London,Ontario N6C 1E8
Canada

Company Activities, Device Classes / Activités de la compagnie, Classes d'instruments

Manufacturer / Fabricant	Importer / Importateur	Distributor / Distributeur
Class I / Classe I		

Compliance Standard / Conformité de la norme

Food and Drugs Act / Loi sur les aliments et drogues

Medical Devices Regulations / Reglement sur les instruments medicaux

Inspection Type / Type d'inspection

Domestic - New - Onsite / Domestique - Nouvelle - Sur place

Inspection Start Date / Date du début de l'inspection

2019-11-05

Closing Meeting Date / Date de réunion de clôture d'inspection

2019-11-07

Telephone Number/ Numéro de téléphone:	Fax Number / Numéro de télécopieur:
519-488-6475	

Emergency Number / Numéro d'urgence:	Internet Address / Adresse Internet: glia.org

Contact Information / L'information de contact

Name of Most Senior Official / Nom du gestionnaire de rang le plus élevé: Tarek Loubani
Title of Most Senior Official / Titre du gestionnaire de rang le plus élevé: Owner
Contact Name / Personne-ressource: Tarek Loubani
Title of Contact / Titre de la personne-ressource: Owner
Contact Phone Number / Numéro de téléphone de la personne-ressource: 519-488-6475
Contact Fax Number / Numéro de fax de la personne-ressource:
Contact E-mail Address / Adresse de courriel de la personne-ressource: tarek@tarek.org

Rating / Evaluation

C	Medical Devices / Instruments médicaux
NC	
NR	

Observations / Observations

Observation # 1
Status / Statut : Open / Ouverte

Risk / Risque : 2
Food & Drugs Act - Devices / Loi et Règlement sur les aliments et drogues - Instruments
Act s.20(1) Prohibition of misrepresentation / Loi s.20(1) Fraude interdit -

The statement “This device (Glia stethoscope) has been validated and is certified by Health Canada as a class I device.” was posted on the company’s website: https://glia.org/stethoscope/
Health Canada does not certify any class I medical device. This statement may create an erroneous impression regarding the device’s design, construction, performance, intended use, quality, character, value, composition, merit or safety.

Observation # 2
Status / Statut : Open / Ouverte
Risk / Risque : 2
MDR - Labelling / RIM - Étiquetage
MDR s.21(1) Multiple label deficiencies / MDR s.21(1) Nonconformités multiples reliées à l'étiquetage -

s.21(1)(b)
The following class I device was available for sale at the company. The manufacturer’s address was not on the label.
- 3D Printed Stethoscope, Identifier: not on the label, Glia, Manufacturer’s address not on the label, IFU not included in the package

s.21(1)(c)
The following class I device was available for sale at the company. The identifier was not on the label.
- 3D Printed Stethoscope, Identifier: not on the label, Glia, Manufacturer’s address not on the label, IFU not included in the package

s.21(1)(i)
The following class I device was available for sale at the company. The instructions for use/device assembly instructions were not included in the labelling.
- 3D Printed Stethoscope, Identifier: not on the label, Glia, Manufacturer’s address not on the label, IFU/device assembly instructions not included in the package

---

Observation # 3
Status / Statut : Open / Ouverte
Risk / Risque : 2
MDR - Establishment licence / RIM - Licence d’établissement
MDR s.45(c) Activities / RIM s.45(c) Activités -

The activities declared in the company's 2019 MDEL annual renewal application are not accurate. They did not distribute class I devices. They only manufacturer class I devices.

Observation # 4
Status / Statut : Open / Ouverte
Risk / Risque : 2
MDR - Complaint handling / RIM - Manutention des plaintes
MDR s.58(a) Investigation procedure / RIM s.58(a) Procédure d’enquête -

The company’s procedure for complaint handling “Glia Inc., Complaint Handling Protocol, June 13, 2015” does not adequately address the requirements of the following regulation.
s.58(a): Effective and timely investigation of reported problems relating to the safety or performance characteristics of the device
Examples of missing elements:
1) Definition of complaint
2) How to collect the complaint information consistently, completely and accurately
3) How to conduct the risk assessment (aspects/criteria to be considered/analysed)
4) How to maintain complaint handling records

5) Cross reference to the procedures for mandatory problem reporting/recall

---

Observation # 5
Status / Statut : Open / Ouverte
Risk / Risque : 2
MDR - Complaint handling / RIM - Manutention des plaintes
MDR s.58(b) Recall procedure / RIM s.58(b) Procédure de rappels -

The company's procedure for recall "Corrective and Recall Action" does not adequately address the requirements of following regulations.
s.58(b): Effective and timely recall
s.64: Time line and required contents of initial recall notice
s.65: Time line and required contents of final recall notice
Examples of missing elements:
1) How to initiate a recall, including the recall strategy (depth of recall, types of recall, time lines to initiate contact with the consignees, how to follow up with the non-responders, how to conduct REC, etc.)
2) Contents of s.64 notice
3) Time line to submit s.64 notice
4) Time line and contents for s.65 notice

Observation # 6
Status / Statut : Open / Ouverte
Risk / Risque : 3
MDR - Establishment licence / RIM - Licence d'établissement
MDR s.45(d) Names of manufacturers / RIM s.45(d) Noms des fabricants des instruments médicaux importés ou distribués -

The suppliers listed in the company's 2019 MDEL annual renewal application is not accurate.
They did not sell devices for the following manufacturers.
1) London Health Services Centre/UWO, Dept. of Emergency Medicine, 339 Windermere Road, University Hospital, London, ON N6A 5A5
2) London Health Science Centre – Victoria Campus, 800 Commissioners Road East, London, ON N6A 5W9

Observation # 7
Status / Statut : Open / Ouverte
Risk / Risque : 3
MDR - Establishment licence / RIM - Licence d'établissement
MDR s.45(g) Distribution, complaints, recalls / RIM s.45(g) Distribution, plaintes, rappels -

The company's procedure for distribution records "Glia Distribution Records Protocol, June 13, 2015" does not adequately address the requirements of following regulations.
s.53: Records shall contain sufficient information to permit complete and rapid withdrawal of the device from the market
s.56: Timely retrieval
Examples of missing elements:
1) Contents of receiving records
2) Time line to retrieve distribution records and step by step process for the retrieval
3) How to back up the distribution records data saved in computers

---

Observation # 8
Status / Statut : Open / Ouverte
Risk / Risque : 3
MDR - Establishment licence / RIM - Licence d'établissement
MDR s.45(j) Listed sites / RIM s.45(j) Adresse de tous les immeubles -

The sites listed in the company's 2019 MDEL annual renewal application are not correct.
The following two addresses were incorrectly listed as sites (buildings) in Canada where procedures described in s.45(g) to 45(i) were in place.

1) Advanced Perioperative Imaging Labe, 200 Elizabeth Street, Toronto, ON M5G 2C4
2) Med-On-Site, 100 Kellogg Lane, London, ON N5W 2T5

Overall Inspection Summary / Sommaire de l'inspection générale

Report Delivered to / Rapport remis à

Response Expected By / Réponse requise avant le

Name / Nom	Signature	Date
Zhihui Cheng - CA-001605	_____	

Total number of pages / Nombre total de pages : _____