

## Appendix B: Foreign Seller Supporting Documentation



Suite #302, Unit #306  
2233 Argentia Rd,  
Mississauga, Ontario, L5N 2X7  
Canada  
Tel: +1 289 499 4569 Ext. 4569  
www.adiramedita.com

October 25, 2022

Center for Drug Evaluation and Research  
Food and Drug Administration  
10001 New Hampshire Avenue  
Hillandale Building, 4<sup>th</sup> Floor  
Silver Spring, MD 20993

**RE: Name and Address of Foreign Seller, Contact Information for Responsible Individuals**

**Name of Foreign Seller:** AdiraMedica Inc

**Address of Foreign Seller:** 2233 Argentia Rd, Suite # 302, Unit # 306,  
Mississauga, Ontario, L5N 2X7 Canada

**Responsible Individuals:**

Name	Contact Information
Arvind Bhandari President & CEO	<u>Redacted</u>
Cal Bains Director Business Development	<u></u>

Sincerely,

Arvind Bhandari  
President & CEO



**Establishment Licence**

**Licence d'établissement**

**Licence No. / No. de la licence  
3-002515-A**

**AdiraMedica Inc.**

**2233 Argentia Road, Suite 302, Unit 306  
Mississauga ON L5N 2X7**

This licence is issued in accordance with the *Food and Drugs Act and Regulations* (Division 1A) for the following activities / Cette licence est délivrée conformément à la *Loi et au Règlement sur les aliments et drogues* (titre 1A) pour les activités et les catégories de drogues suivants :

Category / Catégorie	Activity / Activité	Non-Sterile / Non-Stérile	Sterile / Stérile
Biological / Biologique	Wholesale / Vendre en gros	X	
Prescription Drug List, Schedule G, and/or Narcotics / Liste des drogues sur ordonnance, l'Annexe G, et/ou Stupéfiants	Wholesale / Vendre en gros	X	X
Vaccine / Vaccin	Wholesale / Vendre en gros	X	X

1 - if applicable / s'il y a lieu :

«Biological» includes drugs listed in Schedule D to the Act, other than vaccines or whole blood and its components / « Biologique » inclut les drogues visée à l'annexe D de la Loi, autre que les vaccins ou le sang total et ses composants

«Radiopharmaceutical» includes drugs listed in Schedule C to the Act / « Radiopharmaceutique » inclut les drogues visée à l'annexe C de la Loi

2 - if applicable / s'il y a lieu :


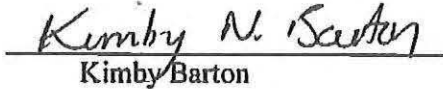
«Distribute» as set out in paragraph C.01 A.003 (a) and/or (b) / « Distribuer » à titre de distributeur au sens de l'alinéa C 01A 003 (a) et/ou (b)

«Tests» includes any tests and examinations required under Division 2 / « Analyser » conformément au titre 2

**This licence contains the following additional annex(es) / Cette licence contient les annexes suivantes :**

**Warehouse Annex / Annexe des entrepôts**

**Date of last GMP inspection / Date de la dernière inspection BPF : 2018-05-15**

MINISTER OF HEALTH / MINISTRE DE LA SANTÉ	Countersigned Director General, Regulatory Operations and Regions Branch or designated official Contresigné par Directeur général, Direction générale des opérations réglementaires et des régions ou responsable désigné
	 Issued on / Émise le : 2018-06-01 Kimby Barton

*This licence is the property of the Regulatory Operations and Regions Branch and must be returned upon demand.  
Cette licence appartient à la Direction générale des opérations réglementaires et des régions et doit être retournée sur demande.*

Establishment Licence

Licence No. / No. de la licence  
3-002515-A

Licence d'établissement

## Warehouse Annex / Annexe des entrepôts

Pursuant to C.01A.008(2)(b) of the *Food and Drug Regulations*, the holder of this establishment licence is authorized to store the category(ies) of drugs, as approved on the first page of this licence, at the following Canadian building(s).

En vertu de l'article C.01A.008(2)(b) du *Règlement sur les aliments et drogues*, le détenteur de cette licence est autorisé d'entreposer les catégories de drogues, tel qu'approuvé à la première page de cette licence, dans les bâtiments canadiens suivants.

Warehouse Name / Nom d'entrepôt	Address / Adresse
Bioscript Logistics Inc.	3330 Ridgeway Drive, Unit 12, Mississauga, ON, L5L 5Z9
Kuehne + Nagel Ltd.	2300 Hogan Drive, Mississauga, ON, L5N 0C8

## Drug & health product inspections

### Licensing information

<b>Establishment name:</b>	AdiraMedica Inc.
<b>Address:</b>	2233 Argentia Road, Suite 302, Unit 306 Mississauga, Ontario Canada L5N 2X7
<b>Reference number:</b>	509997
<b>Site:</b>	A
<b>Licence number:</b>	3-002515
<b>Currently licensed:</b>	Yes
<b>Activities(categories):</b>	<ul style="list-style-type: none"> <li>Wholesale (Prescription Drug List, Schedule G, and/or Narcotics or a drug containing cannabis as defined in subsection 2(1) of the Cannabis Act.)</li> <li>Wholesale (Vaccine)</li> <li>Wholesale (Biological)</li> </ul>
<b>Terms and conditions:</b>	No

### Inspection information

Inspection:	Inspection start date	Rating	Type of inspection
	2019-05-06	<u>Compliant</u>	GMP Domestic - Regular Inspection
	2018-05-15	<u>Compliant</u>	GMP Domestic - Initial Inspection

Date modified: 2016-11-08

## Drug & health product inspections


### Inspection report card summary

[Initial inspection deficiencies report](#)

Establishment name	Reference number	Inspection start date	Type of inspection	Inspection rating
<a href="#">AdiraMedica Inc.</a>	509997	2018-05-15	GMP Domestic - Initial Inspection	Compliant

#### Summary of observations

 Filter items  Showing 1 to 1 of 1 entries Show  entries

Observation number 	Regulation 	Summary of observation 
1	C.02.015 - Quality control department	<ul style="list-style-type: none"> <li>The handling of standard operating procedures for good manufacturing practices was inadequate.</li> </ul>

#### Inspection outcome

Inspection resulted in a Compliant rating. The site has been determined to be in Compliance with Part C, Division 2 of the Food and Drug Regulations. Ratings are the result of observations made by Health Canada based on a reasonable belief at a particular point in time during the course of an inspection that the company was conducting the regulated activity / activities in compliance with the Food and Drugs Act or its Regulations.

#### Measures taken by Health Canada

- Initial inspection in relation to a Drug Establishment Licence (DEL) application. A DEL was issued.

Date modified: 2016-11-08

## Drug & health product inspections




### Inspection report card summary

[Initial inspection deficiencies report](#)

Establishment name	Reference number	Inspection start date	Type of inspection	Inspection rating
<a href="#">AdiraMedica Inc.</a>	509997	2019-05-06	GMP Domestic - Regular Inspection	Compliant

#### Summary of observations

 Filter items  Showing 1 to 3 of 3 entries Show  entries

Observation number 	Regulation 	Summary of observation 
1	C.02.011 - Manufacturing control	<ul style="list-style-type: none"> <li>Investigations into deviations, reports, and/or follow-up actions were inadequate.</li> </ul>
2	C.02.014 - Quality control department	<ul style="list-style-type: none"> <li>The assessment, documentation, and/or procedures for considering the resale of returned drugs were inadequate.</li> </ul>
3	C.02.015 - Quality control department	<ul style="list-style-type: none"> <li>The guidelines and/or procedures were inadequate in ensuring storage and/or transportation conditions would maintain the quality and safe distribution of the drug.</li> </ul>

#### Inspection outcome

Inspection resulted in a Compliant rating. The site has been determined to be in Compliance with Part C, Division 2 of the Food and Drug Regulations. Ratings are the result of observations made by Health Canada based on a reasonable belief at a particular point in time during the course of an inspection that the company was conducting the regulated activity / activities in compliance with the Food and Drugs Act or its Regulations.

#### Measures taken by Health Canada

- Drug Establishment Licence (DEL) was maintained.

Date modified: 2016-11-08

Health Product Compliance Directorate  
GMP Inspection, Central  
2301 Midland Ave  
Toronto, ON M1P 4R7

February 15, 2024

*Sent by email*

File number: 82740

BioScript Logistics Inc.  
3278 South Service Road West  
Unit 5  
Oakville ON L6L 0B1

Attention: Mona Salesse, Director, Scientific Affairs

**Subject: Notice of Compliant Rated Inspection Exit Notice – BioScript Logistics Inc.**

This letter is to inform you of the outcome of the inspection of your establishment on February 6, 2024. Attached to this letter is the rated inspection exit notice, which confirms that your establishment has received a compliant (C) rating.

Our inspection noted contraventions to the GMP requirements set out in Part C, Division 2 of the *Food and Drug Regulations* (FDR). The attached inspection exit notice summarizes the observations made during the inspection, as discussed during the exit meeting of February 15, 2024.

These observations are categorized based on our [Risk classification guide for drug good manufacturing practices observations \(GUI-0023\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/risk-classification-drug-gmp-observations-0023.html) available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/risk-classification-drug-gmp-observations-0023.html>.

For all observations risk rated as risk 1 (critical) and risk 2 (major), you must submit a detailed written response describing both the short and long term corrective actions and preventative actions (CAPAs) you will take, or have taken to address these observations, including reasonable timeframes for their implementation. The written CAPA plan must be sent to Health Canada by March 14, 2024. Health Canada will evaluate the acceptability of your plan (actions and timelines) and will communicate the results of our evaluation. Should your CAPA plan be found



unacceptable, you will be afforded a single opportunity to revise the proposed plan and re-submit it to Health Canada for further review.

Please be reminded that you are also required to implement CAPAs for observations risk rated as risk 3 (other), but you do not have to submit a written CAPA plan for these observations.

Please note that your inspection exit notice may be subject to an internal review for quality assurance purposes. You will be notified of any changes to the observations made as a result of this review.

As per subsection C.01A.008(4) of the *Food and Drug Regulations*, we are recommending to add terms and conditions to your drug establishment licence. If the recommendation is accepted the licence will be issued with the terms and conditions.

Should you wish to raise any concerns regarding the content of the attached inspection exit notice, you have 10 business days from the date of this letter to bring your concerns to our attention. Please note that Health Canada will consider only the information that was presented during the inspection, which concluded at the exit meeting which took place on February 15, 2024. If you choose to raise concerns, you must submit a comprehensive written report explaining your position, along with any applicable supporting information, to:

Nicole Proctor, Acting Regional GMP Manager  
Health Product Inspection and Licensing Division  
Email: [Nicole.Proctor@hc-sc.gc.ca](mailto:Nicole.Proctor@hc-sc.gc.ca)

Should you have any questions please do not hesitate to contact the undersigned. We thank you for your cooperation.

Regards,



Digitally signed by Chan, Tiffany  
DN: c=CA, o=GC, ou=HC-SC,  
cn=Chan, Tiffany  
Date: 2024.02.15 12:04:17 -05'00'

Tiffany Chan  
Regional Regulatory Compliance and Enforcement Officer, Health Canada, ROEB, (Central)

Attachment: Rated inspection exit notice

[Drug Databases \(https://www.fda.gov/Drugs/InformationOnDrugs/default.htm\)](https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# Drug Establishments Current Registration Site

[New Search \(default.cfm\)](#)

Search Results for **adira**

[CSVExcel](#)

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
AdiraMedica Inc	3014691731	202125744	SIP FOREIGN SELLER;	2233 Argentia Rd Suite 302, Unit 306, Mississauga, Ontario L5N 2X7, Canada (CAN)	12/31/2024

Showing 1 to 1 of 1 entries

[Previous](#)[Next](#)

Data Current through: Tuesday, Nov 21, 2023

[Return to Drug Firm Annual Registration Status Home Page \(default.cfm\)](#)