Appendix B: Foreign Seller Supporting Documentation

AdiraMedica Inc.

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

October 25, 2022

Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Avenue
Hillandale Building, 4th 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	Redacted
Cal Bains Director Business Development	

Sincerely,

Arvind Bhandari
President & CEO

Health Canada / Santé Canada

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 distribuer au sens de l'alinéa C.01A.003 (a) et/ou (b)
«Test» includes any tests and examinations required under Division 2 / « Analyser » conformement 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
Establishment Licence Licence d'établissement Health Canada / Santé Canada Canada	Kimby N. Barton Kimby Barton Issued on / Émise le : 2018-06-01

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.

Canada

Health Canada Santé Canada

Establishment Licence **Licence d'établissement**

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

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

Canada

Government of Canada / Gouvernement du Canada

Drug & health product inspections

Licensing information

Establishment name: AdiraMedica Inc.

Address: 2233 Argentia Road, Suite 302, Unit 306
Mississauga, Ontario
Canada
L5N 2X7

Reference number: 509997

Site: A

Licence number: 3-002515

Currently licensed: Yes

Activities(categories):

- Wholesale (Prescription Drug List, Schedule G, and/or Narcotics or a drug containing cannabis as defined in subsection 2(1) of the Cannabis Act.)
- Wholesale (Vaccine)
- Wholesale (Biological)

Terms and conditions: No

Inspection information

Inspection:

Inspection start date	Rating	Type of inspection
2019-05-06	Compliant	GMP Domestic - Regular Inspection
2018-05-15	Compliant	GMP Domestic - Initial Inspection

Date modified: 2016-11-08

Government of Canada / Gouvernement du Canada

Drug & health product inspections

Inspection report card summary

Initial inspection deficiencies report

Establishment name	Reference number	Inspection start date	Type of inspection	Inspection rating
AdiraMedica Inc.	509997	2018-05-15	GMP Domestic - Initial Inspection	Compliant

Summary of observations

Filter items

Showing 1 to 1 of 1 entries Show 10 entries

Observation number	Regulation	Summary of observation
1	C.02.015 - Quality control department	• The handling of standard operating procedures for good manufacturing practices was inadequate.

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

Government of Canada / Gouvernement du Canada

Drug & health product inspections

Inspection report card summary

Initial inspection deficiencies report

Establishment name	Reference number	Inspection start date	Type of inspection	Inspection rating
AdiraMedica Inc.	509997	2019-05-06	GMP Domestic - Regular Inspection	Compliant

Summary of observations

Filter items

Showing 1 to 3 of 3 entries **Show** 10 **entries**

Observation number	Regulation	Summary of observation
1	C.02.011 - Manufacturing control	• Investigations into deviations, reports, and/or follow-up actions were inadequate.
2	C.02.014 - Quality control department	• The assessment, documentation, and/or procedures for considering the resale of returned drugs were inadequate.
3	C.02.015 - Quality control department	• The guidelines and/or procedures were inadequate in ensuring storage and/or transportation conditions would maintain the quality and safe distribution of the drug.

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)* 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

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

Regards,

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

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

Attachment: Rated inspection exit notice

Drug Establishments Current Registration Site

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
AdiraMedica Inc	3014691731	202125744	SIP FOREIGN SELLER	2233 Argentia Rd Suite 302, Unit 306, Mississauga, Ontario L5N 2X7, Canada (CAN)	12/31/2025

Health Canada Santé Canada

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

July 30, 2024

Sent by email

File number: 83946

AdiraMedica Inc.
2233 Argentia Road, Suite 302, Unit 306
Mississauga, ON, L5N 2X7

Attention: Ashwin Narotam, President & Senior Consultant (Ardent Consultants)

Subject: Notice of CAPA Plan Evaluation - Acceptable – AdiraMedica Inc.

This letter is to inform you of the evaluation of your corrective action and preventative action (CAPA) plan to address the observations noted during the inspection of your establishment from June 10, 2024 to June 12, 2024, which was assigned a compliant (C) rating.

Your CAPA plan submitted on July 19, 2024 has been evaluated by Health Canada and has been deemed to be acceptable at this time.

This inspection is now considered concluded and unless requested, you are not expected to submit any further information related to this inspection. However, you are required to notify Health Canada by contacting the undersigned, should the timelines or content included in your CAPA plan change.

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

Regards,

Digitally signed by Paiement, Shannon
DN: c=CA, o=GC, ou=HC-SC, cn=Paiement, Shannon
Date: 2024.07.30 09:48:47 -04'00'

Shannon Paiement
Regional Regulatory Compliance and Enforcement Officer, Health Canada, ROEB, Central

Canada

Drug & health product inspections

Inspection report card summary

Initial inspection deficiencies report

Establishment name	Reference number	Inspection start date	Type of inspection	Inspection rating
AdiraMedica Inc.	509997	2024-06-10	GMP Domestic	Compliant

Summary of observations

Filter items Showing 1 to 4 of 4 entries**Show** 10 **entries**

Observation number	Regulation	Summary of observation
1	C.02.012 - Manufacturing control	• The written procedures for recalls were inadequate.
2	C.02.015 - Quality control department	• The examination and/or approval of fabrication, packaging, labelling, testing, storage, and/or the transportation method and procedures by the person in charge of the quality control department before implementation was inadequate.
3	C.02.020 - Records	• The traceability, legibility, documentation, formatting, and/or the accuracy of records was inadequate.

Observation number	Regulation	Summary of observation
4	C.02.024 - Records	• The handling of standard operating procedures for good manufacturing practices was inadequate.

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 was maintained.

Date modified: 2016-11-08

Health Canada Santé Canada

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.

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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)* 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.

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Nicole Proctor, Acting Regional GMP Manager
Health Product Inspection and Licensing Division
Email: 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, Tiffiny
DN: c=CA, o=GC, ou=HC-SC,
cn=Chan, Tiffiny
Date: 2024.02.15 12:04:17 -05'00'

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

Attachment: Rated inspection exit notice

Drug & health product inspections

Inspection report card summary

Initial inspection deficiencies report

Establishment name	Reference number	Inspection start date	Type of inspection	Inspection rating
BioScript Logistics Inc.	510829	2024-02-06	GMP Domestic	Compliant

Summary of observations

Filter items

Showing 1 to 2 of 2 entries **Show** 10 **entries**

Observation number	Regulation	Summary of observation
1	C.02.014 - Quality control department	• Investigations into deviations, reports, and/or follow-up actions were inadequate.
2	C.02.020 - Records	• The controls put in place for electronic signatures were inadequate. • The establishment and/or the maintenance of a data governance plan was inadequate.

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 was amended.

Date modified: 2016-11-08