Health Canada Santé Canada

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E-Manufacturer's Certificate to Export Licensed Medical Devices from Canada - Certificate of Free Sale (FRM-0539)

We, the undersigned manufacturer of the following devices:

Part 1 – Devices

(include the MDEL information for your Class I medical device and the MDL information for your Class II, III and IV medical devices)

Medical Devices Establishment Licence (MDEL)

MDEL # (Class I medical devices):	Device(s) name:
12663	Immunohistochemistry (IHC) Auto Stainer LC-AS20 with accessories (reagent bottles, special reagents bottles, reagent bottles rack)

Medical Device Licence (MDL)

MDL #:	Device identifier: (model/catalogue detail)	MDL Class #: (II, III, IV)	Device(s) name:
n/a			

Interim Order (IO) authorizations

IO authorization ID #:	Device(s) name:	IO authorization date: (yyyy-mm-dd)	Device identifier #:
n/a			

Do hereby certify that:

a) each device is manufactured, produced and sold in Canada in accordance with the requirements of Canada's *Food and Drugs Act* and the *Medical Device Regulations* thereunder

b) tests have been conducted for each device and the tests indicate that the nature of the benefits claimed to be obtained through the use of each device and the performance characteristics of each device are justified

Part 2 - Name and address of manufacturer

Company ID (6 digits):	Name:
155311	Labex Canada Inc.

Street address: 28-1228 Gorham St.

City:	Province:	Postal code:
Newmarket	Ontario	L3Y8Z1

Part 3 – Signature of authorized person (print name and title of the authorized person)

Name:	Signature:
Peter Molnar QA/RA Manager	Digitally signed by Peter Molnar Labex Date: 2024.07.18 12:39:08 -04'00'

Canada

Medical Device Licence (MDL) – Additional			
MDL#	**Device identifier** (model/catalogue detail)	**MDL Class # (II, III, IV)**	**Device(s) name**
n/a			

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For Office Use Only

Health Canada
Regulatory Operations and Enforcement Branch

It is hereby certified that:

a. Devices manufactured, produced and sold in the manner above described would not, by reason of the method of manufacture thereof, be in violation of the Act and the Regulations thereunder

b. Devices manufactured and sold in compliance with the Act and the Regulations may be exported without restriction

c. Devices listed are registered and sold in Canada and are of free sale

Guira, Elise

Digitally signed by Guira, Elise
DN: C=CA, O=GC, OU=HC-SC, CN="Guira, Elise"
Reason: I attest to the accuracy and integrity of this document
Date: 2024.07.26 15:35:31 -04'00'

Medical Devices Establishment Licence Unit
Medical Devices and Clinical Compliance Directorate
Regulatory Operations and Enforcement Branch
Health Canada

Disclaimer: This certificate is valid only if signed by Health Canada with all pages included. The validity of the signature can only be viewed electronically.

Privacy Notice

The personal information you provide to Health Canada will be used by the Regulatory Operations and Enforcement Branch under the *Food and Drug Act* and the *Medical Devices Regulations* and handled in accordance with the *Privacy Act*.

Why are we collecting your personal information? We require your personal information, including your name, title and manufacturer information to process your request for a Manufacturer's Certificate to Export Licensed Medical Devices from Canada.

Will we use or share your personal information for any other reason? We may also share your personal information with Global Affairs Canada to authenticate the certificate.

What happens if you don't want to provide your personal information? Failure to provide the requested information may prevent the processing of your request for a Manufacturer's Certificate to Export Licensed Medical Devices from Canada.

What are your rights? You have the right to access and request a correction and/or notation to your personal information. You also have a right to complain to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights or about how we handle your personal information, please contact us by email at mce.questions-cfe@hc-sc.gc.ca.