U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Paula Katz
Director Quality Assurance
Novodiax, Inc.
3517 Breakwater Avenue
Hayward, CA 94545

JUN 16 2020

Dear Ms. Paula Katz:

This is in response to your Certificate to Foreign Government request. This Certificate to Foreign Government only attests to the status of your product under the Federal Food, Drug, and Cosmetic Act. You are responsible for assuring that your product, when exported to these countries, is in compliance with all other US laws and regulations regarding export of such products to these specific countries. Enclosed are the certificates that you requested. If you have any additional questions, please email CDRHCECATS@fda.hhs.gov or call (301) 796-7400, option 3.

Exports Team
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

Enclosure:
1 Certificate(s)
10485-6-2020

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Certificate No. 10485-6-2020

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(One Page)	(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from June 16, 2020 to June 15, 2022.

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Certificate No. 10485-6-2020
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

Novodiax, Inc.
3517 Breakwater Ave.
Hayward, CA USA 94545

Name of Manufacturer

NOVODIAX, INC.
3517 Breakwater Ave
Hayward, CA USA 94545

----END OF MANUFACTURER/DISTRIBUTOR LIST----

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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer

NOVODIAX, INC.
3517 Breakwater Ave
Hayward, CA USA 94545

Name of Product(s)

ihcDirect Pan-CK 4Abs
ihcDirect AE1/AE3 Abs
ihcDirect Cytokeratin 5 Kits
ihcDirect Calponin Kits
ihcDirect CD45 Ab
ihcDirect CEA Ab
ihcDirect SMMS-1 Kits
ihc DAB 1:1 Kits
ihcDirect CD20 Ab
ihcDirect Vimentin Ab
ihcDirect Immunohistochemistry Kits
ihcDirect Ki67 Ab
ihcDirect EMA Ab
DAB Kit
ihcDirect Mart-1 Kits
ihcDirect Cytokeratin 8/18 Kits
ihcDirect Cytokeratin 7 Kits
ihcDirect Podoplanin Kits
ihcDirect GFAP Kits
ihcDirect CK19 Ab
ihcDirect CK20 Ab
ihc Blocker
ihc Wash Buffer Kit (10x)
ihc Magenta 1:1 Kit

----------END OF PRODUCT LIST----------