



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](mailto: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



**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)**

See Attached List

(One Page)

**Name of Manufacturer/Distributor, Address**

See Attached List

(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**

Novodiag, 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----





**Certificate No. 10485-6-2020**

**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-----

