



**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

Certificate No. CFG-NE1062-5-2024-1

**CERTIFICATE TO FOREIGN GOVERNMENT
FOR DEVICE NOT EXPORTED FROM THE UNITED STATES**

The U.S. Food and Drug Administration (FDA) certifies the following information concerning the device(s) listed below to be shipped from CHINA into foreign countries.

Name of Device(s)

See Attached List

(Three Pages)

Name of Manufacturer, Address

See Attached List

(One Page)

The device(s) described above (and the manufacturing site(s) which produces it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

It is certified that the above device(s) may be marketed in the United States of America at this time. The manufacturing establishment(s) in which the device(s) is produced is subject to periodic inspections.

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 May 23, 2024 to May 22, 2026.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



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Certificate to Foreign Government for Device not Exported from the United States - Name of Manufacturer

Attachment Page 1 of 1

Name of Owner Operator

Celnovte Biotechnology Co., Ltd
NO. 1 Cuizhu Street, Bldg 109, Hi-tech District , Zhengzhou
City, Henan, China
zhengzhou, Henan
CHINA 450000

Name of Manufacturer

CELNOVTE BIOTECHNOLOGY CO., LTD
NO. 1 Cuizhu Street, Bldg 109, Hi-tech District , Zhengzhou
City, Henan, China
zhengzhou, Henan
CHINA 450000

----END OF MANUFACTURER LIST----





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Name of Owner Operator

Celnovte Biotechnology Co., Ltd
NO. 1 Cuizhu Street, Bldg 109, Hi-tech District , Zhengzhou City, Henan, China
zhengzhou, Henan
CHINA 450000

Name of Manufacturer

CELNOVTE BIOTECHNOLOGY CO., LTD
NO. 1 Cuizhu Street, Bldg 109, Hi-tech District , Zhengzhou City, Henan, China
zhengzhou, Henan
CHINA 450000

Name of Product(s)

Fully Automatic Immunohistochemistry Stainer (CNT300) - SLIDE STAITNER
Fully Automatic Immunohistochemistry Stainer (CNT330) - SLIDE STAITNER
Fully Automatic Special Stainer and Coverslipper - SLIDE STAITNER
Alpha-1-Fetoprotein (C1B1), MAb - REAGENTS
AMACR/p504s (C7H4), MAb - REAGENTS
Annexin A1 (C5F8), MAb - REAGENTS
Androgen Receptor (C1B4), MAb - REAGENTS
Bcl-2 (C7B8), MAb - REAGENTS
Bcl-6 (C4A4), MAb - REAGENTS
CA125 (C6E8), MAb - REAGENTS
Carbonic Anhydrase 9 /(CAIX) (C5C6), MAb - REAGENTS
Calcitonin (C1C2), MAb - REAGENTS
Calponin (C6A12), MAb - REAGENTS
CD10 (C6D1), MAb - REAGENTS
CD138(C5G6), MAb - REAGENTS
CD163 (C2F5), MAb - REAGENTS
CD1a (C1E1), MAb - REAGENTS
CD2 (C3G8), MAb - REAGENTS
CD20 (C4A11), MAb - REAGENTS
CD23 (C3B11), MAb - REAGENTS
CD3 (C3E7), MAb - REAGENTS
CD30 (C5E10), MAb - REAGENTS
CD31 (C6E5), MAb - REAGENTS
CD38 (C3G3), MAb - REAGENTS
CD5 (C6A10), MAb - REAGENTS
CD56 (C5A2), MAb - REAGENTS
CD68 (C2F10), MAb - REAGENTS
CD79a (C4C4), MAb - REAGENTS
CD8 (C2B11), MAb - REAGENTS
CDX-2 (C2X5), RMAb - REAGENTS
CD66e/CEA (C3G5), MAb - REAGENTS
Chromogranin A (C1E8), MAb - REAGENTS
Cytokeratin14 (C2D11), MAb - REAGENTS
Cytokeratin18 (C6B9), MAb - REAGENTS
Cytokeratin 19 (C8G9), MAb - REAGENTS
Cytokeratin 20 (C7C11), MAb - REAGENTS
Cytokeratin 5&6 (C6H1/C1C8), MAb - REAGENTS
Cytokeratin 7 (C1C10), MAb - REAGENTS
Cytokeratin 8 (C7E10), MAb - REAGENTS
Cytokeratin 8/18 (C7E10/C6B9), MAb - REAGENTS
Calretinin (C5G4), MAb - REAGENTS
Desmin (C3B7), MAb - REAGENTS
DOG1 (C2E3), MAb - REAGENTS
EGFR (C1E7), MAb - REAGENTS
Estrogen Receptor (C6H7), MAb - REAGENTS





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Galectin-3 (C6C10), MAb - REAGENTS
Glial Fibrillary Acidic Protein (C2C6), MAb - REAGENTS
Glutamine Synthetase (C6E12), MAb - REAGENTS
Human Chorionic Gonadotropin (C5C5), MAb - REAGENTS
HMB-45 (C6C9), MAb - REAGENTS
Hepatocyte Specific Antigen (HSA) (C4F5), MAb - REAGENTS
Inhibin- α (C6H12), MAb - REAGENTS
Kappa Light Chain (C8H10), MAb - REAGENTS
Ki-67 (C3G4), MAb - REAGENTS
Lambda Light Chain (C8A6), MAb - REAGENTS
Mammaglobin (C7G9), MAb - REAGENTS
MSH2 (C2G3), MAb - REAGENTS
MSH6 (C5D11), MAb - REAGENTS
MUC-1 (C3C1), MAb - REAGENTS
MUC5AC (C1H10), MAb - REAGENTS
MUM1 (C6H9), MAb - REAGENTS
Myoglobin (C3H2), MAb - REAGENTS
Myosin, Smooth Muscle(C1B2), MAb - REAGENTS
Napsin A (C2C2), MAb - REAGENTS
NSE (C8E5), MAb - REAGENTS
Oct3/4 (C4E6), MAb - REAGENTS
p16 (C4H6), MAb - REAGENTS
p40 (C3B4), MAb - REAGENTS
p53 (C2H10), MAb - REAGENTS
p57 (C2G2), MAb - REAGENTS
p63 (C2C10), MAb - REAGENTS
PAX-5 (C2F9), MAb - REAGENTS
PD-1 (C5H11), MAb - REAGENTS
Prolactin (C8E12), MAb - REAGENTS
PSA (C2C12), MAb - REAGENTS
Parathyroid Hormone(C2G9), MAb - REAGENTS
S100P (C5B10), MAb - REAGENTS
SALL4 (C2E8), MAb - REAGENTS
SMA (C1C1), MAb - REAGENTS
SOX-10 (C6E11), MAb - REAGENTS
Surfactant Protein A (C3F12), MAb - REAGENTS
Synaptophysin (C9D11), MAb - REAGENTS
Terminal Deoxynucleotidyl Transferase (TdT) (C2C8), MAb - REAGENTS
Thyroglobulin (C6D6), MAb - REAGENTS
TLE1 (C3E9), MAb - REAGENTS
TOP2A (C4E3), MAb - REAGENTS
TPO (C3B12), MAb - REAGENTS
TTF-1 (C7H7), MAb - REAGENTS
Villin (C2E10), MAb - REAGENTS
Vimentin (C2B4), MAb - REAGENTS
Claudin 18.2 (C7X3), RMAb - REAGENTS
HER2 (C1F7), MAb - REAGENTS
PD-L1 (C9C9), MAb - REAGENTS
Progesterone Receptor (C4D10), MAb - REAGENTS
Smooth Muscle Myosin (C1X9), RMAb - REAGENTS
AMACR/p63/CK HMW Cocktail Antibody - REAGENTS
TTF-1/Napsin A Cocktail Antibody - REAGENTS
CK5/6/p40 Cocktail Antibody - REAGENTS
CK5/6/TTF-1 Cocktail Antibody - REAGENTS
NapsinA&p40 Cocktail Antibody - REAGENTS
CK5/6&p63 Cocktail Antibody - REAGENTS
Calponin&p63 Cocktail Antibody - REAGENTS
Myosin Heavy Chain/p63 Cocktail Antibody - REAGENTS





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E-Cadherin/p120 Cocktail Antibody - REAGENTS
CK7/Calponin/p63 Cocktail Antibody - REAGENTS
CK7/Myosin Heavy Chain/p63 Cocktail Antibody - REAGENTS
p53/CK20 Cocktail Antibody - REAGENTS
CD4/CD8 Cocktail Antibody - REAGENTS
PAX5/CD3 Cocktail Antibody - REAGENTS
CD138/MUM1 Cocktail Antibody - REAGENTS
SATB2/CK20 Cocktail Antibody - REAGENTS
pan-CK/Desmin Cocktail Antibody - REAGENTS
pan-CK/p63 Cocktail Antibody - REAGENTS
Wash Solution 10X Concentrate - BUFFER
Frozen Section Wash Buffer (10X) - BUFFER
MicroStacker™ Flex Polymer Detection Kit - REAGENTS
MicroStacker™ Plus Polymer Detection Kit - REAGENTS
Dewax Solution - BUFFER
Antigen Retrieval Solution I - BUFFER
Antigen Retrieval Solution II - BUFFER
Probe Cleaning Kit - BUFFER
DAB Chromogen Kit - BUFFER
MicroStacker™ Polymer Detection Kit, Universal (3 Components) - REAGENTS
MicroStacker™ Polymer Detection Kit, Universal (4 Components) - REAGENTS
MicroStacker™ Polymer Detection Kit, Universal (5 Components) - REAGENTS
MicroStacker™ Polymer Detection Kit, Enhanced, 1-Step (3 Components) - REAGENTS
MicroStacker™ Polymer Detection Kit, Enhanced, 1-Step (4 Components) - REAGENTS
MicroStacker™ Polymer Detection Kit, Enhanced, 1-Step (5 Components) - REAGENTS
MicroStacker™ Polymer Detection Kit, Enhanced, 2-Step (4 Components) - REAGENTS
MicroStacker™ Polymer Detection Kit, Enhanced, 2-Step (5 Components) - REAGENTS
MicroStacker™ Polymer Detection Kit, Enhanced, 2-Step (6 Components) - REAGENTS
Antigen Retrieval Solution (Citrate) - BUFFER
Antigen Retrieval Solution (EDTA) - BUFFER
DualStacker™ TM Detection Kit (Dual staining I) - REAGENTS
DualStacker™ TM Detection Kit (Dual staining II) - REAGENTS
MicroStacker™ TM AP Polymer Detection Kit (Red) - REAGENTS
PolyStacker™ anti-Rabbit detection kit - REAGENTS
PolyStacker™ anti-Mouse detection kit - REAGENTS
Frozen Section Fixative - REAGENTS
Kappa Chain Detection Kit (Instrument) - REAGENTS
Kappa&Lambda Chain Double Stain Kit - REAGENTS
EBER /CD3 Double stain Kit - REAGENTS
Cytomegalovirus (CMV) Detection Kit - REAGENTS
-----END OF PRODUCT LIST-----

