



Certificate No. 5130-2-2023

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

(Eight Pages)

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 February 13, 2023 to February 12, 2025.





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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Manufactured for Owner Operator

Sakura Global Holding Company
1750 W 214th St
Torrance, CA
USA 90501

Name of Manufacturer/Distributor

SAKURA FINETEK U.S.A., INC.
1750 W 214th St
TORRANCE, CA
USA 90501

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





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Name of Manufacturer/Distributor

SAKURA FINETEK U.S.A., INC.

1750 W 214th St

TORRANCE, CA

USA 90501

Name of Product(s)

GROSSING AND TRIMMING

Tissue-Tek® Accu-Edges Countertop Work Station

Tissue-Tek® Accu-Edge® Elevating Grossing Station

Tissue-Tek® Accu-Edge® Pathology Work Station

Tissue-Tek® Accu-Edge® Grossing Station

Tissue-Tek® Accu-Edge® Grossing Forks

Tissue-Tek® Accu-Edge® Grossing Boards

-All sizes and models including All Grossing Boards and Forks

Consumables

Tissue-Tek® Processing/Embedding Cassette System

Tissue-Tek® Uni-Cassette® Standard Cassette System

Histo-Tek® Cassettes

Tissue-Tek® Uni-Cassette®

Tissue-Tek® Paraform® Sectionable Cassette System

Tissue-Tek® Paraform® LP Stacked Frames

Tissue-Tek® Paraform® Tubed Frames

Tissue-Tek® Paraform® Tissue Orientation Gels

Tissue-Tek® Accu-Edge® Autopsy Knife Series

Tissue-Tek® Accu-Edge® Trimming Knife Series

Tissue-Tek® Accu-Edge® Dissecting Scalpel Series

Tissue-Tek® Accu-Edge® Replaceable Blades Scissors

Accu-Edge® Disposable Microtome Blades

Accu-Edge® Blade Holders

Tissue-Tek® FormaGO® Formalin Safety System

LABELING AND IDENTIFICATION

Instruments

Tissue-Tek® AutoWrite® Cassette Printer

Tissue-Tek® SmartWrite® Cassette Printer

Tissue-Tek® SmartWrite® Cassette Printer with AutoLoader

Tissue-Tek® SmartWrite® Slide Printer

Consumables

Tissue-Tek® SmartWrite® White Frosted Slide

Tissue-Tek® SmartWrite® White Frosted Slide - Charged

-All accessories Included

TISSUE PROCESSING

Instruments

Tissue-Tek Xpress® x120 Rapid Tissue Processor

Tissue-Tek Xpress® x50 Rapid Tissue Processor

Tissue-Tek VIP® 6 AI Vacuum Infiltration Processors

Tissue-Tek VIP® 6 Vacuum Infiltration Processors

Tissue-Tek VIP® 5

Histo-Tek® VP1

Consumables

Tissue-Tek VIP® Fixative

Tissue-Tek ClearFIX®

Tissue-Tek Xpress® Pre-Processing Solution

Tissue-Tek Xpress® Pre-Processing Fixative

Tissue-Tek Xpress® Molecular Fixative

Tissue-Tek VIP® Paraffin





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Tissue-Tek® Paraform® Processing/Embedding Medium, Formula 3

Tissue-Tek Xpress® x50 Processing Reagent Set

Tissue-Tek Xpress® x120 Processing Reagent Set

-All accessories Included

EMBEDDING

Instruments

Tissue-Tek AutoTEC® Automated Embedding System

Tissue-Tek AutoTEC® a120 Automated Embedding System

Tissue-Tek® TEC™ 5 Tissue Embedding Console System

Tissue-Tek® TEC™ 6

Tissue-Tek® TEC™ Cryo Console

Tissue-Tek® TEC™ Plus Cryo Console

Tissue-Tek® Quick-Ray™ Tissue Microarray System

Consumables

Tissue-Tek® Mold Release Concentrate

Tissue-Tek® Paraform® Base Molds

Tissue-Tek® Quick-Ray™ Punches, Recipient Blocks and Recipient Base Mold

Tissue-Tek® Base Mold System

Tissue-Tek® NanoMold™ Base Molds

Tissue-Tek® Biopsy Bags

-All accessories Included

MICROTOMY AND CRYOTOMY

Instruments

Tissue-Tek AutoSection® Automated Microtome

Tissue-Tek® Cryo3® Flex Cryostat

Accu-Cut® SRM™ 200 Manual Rotary Microtomes

Accu-Cut® SRM™ 300 LT

Tissue-Tek® Cold Plate

Tissue-Tek® Cryo Microtome/Cryostat

Tissue-Tek® Cryo3® Microtome/Cryostat

Tissue-Tek® Cryo3® Plus Microtome/Cryostat

Consumables

Tissue-Tek® Feather® Low Profile Microtome Blades

Accu-Edge® Microtome Blades

Tissue-Tek® Feather® A35 Durable Low Profile Blades

Tissue-Tek® Feather® Paraform® Microtome Blades

Tissue-Tek® Accu-Edge® Microtome Blade System

Tissue-Tek® Accu-Edge® Heavy Duty Blade System

Tissue-Tek® Accu-Edge® High Profile Microtome Blades

Tissue-Tek® O.C.T. Compound

Cryomold®

Specimen Holders

-All accessories Included

STAINING AND COVERSLIPPING

Instruments

Tissue-Tek Genie® Advanced Stainer

Tissue-Tek Prisma® Standard Configuration

Tissue-Tek Prisma® Special Staining Configuration

Tissue-Tek Prisma® Plus standard Configuration

Tissue-Tek Prisma® Plus Special Staining Configuration

Tissue-Tek Prisma® Plus Automated Slide Stainer

Tissue-Tek Prisma® Plus Automated Stainer

Tissue-Tek Prisma® Plus Special Stain Automated Slide Stainer

Tissue-Tek Film® Coverslipper

Tissue-Tek® Glas™ g2 Glass Coverslipper





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Histo-Tek® SL Slide Stainer

Tissue-Tek® DRS 2000®

Consumables

Tissue-Tek® Manual Slide Staining Kit

Tissue-Tek® Coverslipping Film; 60 m, 5 rolls/cs

Tissue-Tek® Glas™ g2 Coverslips and Easy Holder

Tissue-Tek® Glas™ Mounting Medium; 1x16oz.

-All accessories Included

CYTOCENTRIFUGATION

Instruments

Cyto-Tek® Cytology Centrifuge

Cyto-Tek® 2500 Cyto centrifuge

Consumables

Fluid Chambers

DIGITAL IMAGING

Instruments

VisionTek® Digital Microscope

VisionTek® M6 Digital Microscope

IMMUNOHISTOCHEMISTRY (IHC)

Primary Antibodies

Genemed anti-AFP Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-AMACR Rabbit Monoclonal Antibody [13H4], Ready-To-Use
Genemed anti-Bcl-2 Mouse Monoclonal Antibody [Bcl-2-100], Ready-To-Use
Genemed anti-CA19-9 (Sialyl Lewis) Mouse Monoclonal Antibody [SPan-1], Ready-To-Use
Genemed anti-Calponin Mouse Monoclonal Antibody [CALP], Ready-To-Use
Genemed anti-Calretinin Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-CD10 Mouse Monoclonal Antibody [GM003], Ready-To-Use
Genemed anti-CD19 Rabbit Monoclonal Antibody [GR014], Ready-To-Use
Genemed anti-CD20 Mouse Monoclonal Antibody [L26], Concentrate
Genemed anti-CD20 Mouse Monoclonal Antibody [L26], Ready To Use
Genemed anti-CD23 Rabbit Monoclonal Antibody [GR013], Ready-To-Use
Genemed anti-CD3 Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-CD30 Mouse Monoclonal Antibody [Ber-H2], Ready-To-Use
Genemed anti-CD31 (PECAM-1) Mouse Monoclonal Antibody [GM006], Ready-To-Use
Genemed anti-CD34 Mouse Monoclonal Antibody [QBend10], Ready-To-Use
Genemed anti-CD45 (LCA) Rabbit Monoclonal Antibody [GR009], Ready-To-Use
Genemed anti-CD45RO Mouse Monoclonal Antibody [UCHL-1], Ready-To-Use
Genemed anti-CD5 Rabbit Monoclonal Antibody [GR020], Ready-To-Use
Genemed anti-CD56 (NCAM) Mouse Monoclonal Antibody [123C3], Ready-To-Use
Genemed anti-CD68 Rabbit Monoclonal Antibody [GR021], Ready-To-Use
Genemed anti-CD79a Rabbit Monoclonal Antibody [GR019], Ready-To-Use
Genemed anti-CD8 Mouse Monoclonal Antibody [C8/144B], Ready-To-Use
Genemed anti-CDX2 Rabbit Monoclonal Antibody [GR023], Ready-To-Use
Genemed anti-CEA Mouse Monoclonal Antibody [COL-1], Ready-To-Use
Genemed anti-Chromogranin A Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-c-kit (CD117) Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-Cyclin D1 Rabbit Monoclonal Antibody [GR005], Concentrate
Genemed anti-Cyclin D1 Rabbit Monoclonal Antibody [GR005], Ready-To-Use
Genemed anti-Cytokeratin 18 Mouse Monoclonal Antibody [DC-10], Ready-To-Use
Genemed anti-Cytokeratin 19 Mouse Monoclonal Antibody [A53-B/A2.26], Ready-To-Use
Genemed anti-Cytokeratin 20 Mouse Monoclonal Antibody [Ks20.8], Ready-To-Use
Genemed anti-Cytokeratin 5 Mouse Monoclonal Antibody [GM028], Ready-To-Use
Genemed anti-Cytokeratin 5/6 Mouse Monoclonal Antibody [D5/16B4], Ready-To-Use
Genemed anti-Cytokeratin 7 Mouse Monoclonal Antibody [OV-TL 12/30], Ready-To-Use
Genemed anti-Cytokeratin HMW Mouse Monoclonal Antibody [34bE12], Ready-To-Use





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Genemed anti-Cytokeratin Mouse Monoclonal Antibody Cocktail [AE1/AE3], Concentrate
Genemed anti-Cytokeratin Mouse Monoclonal Antibody Cocktail [AE1/AE3], Ready-To-Use
Genemed anti-Desmin Mouse Monoclonal Antibody [GM007], Ready-To-Use
Genemed anti-EGFR Rabbit Monoclonal Antibody [GR018] Concentrate
Genemed anti-EGFR Rabbit Monoclonal Antibody [GR018], Ready-To-Use
Genemed anti-EMA Mouse Monoclonal Antibody [GM008], Ready-To-Use
Genemed anti-Epithelial Cell Adhesion Molecule Mouse Monoclonal Antibody [VU-1D9] Concentrate
Genemed anti-Epithelial Cell Adhesion Molecule Mouse Monoclonal Antibody [VU-1 D9], Ready-To-Use
Genemed anti-Estrogen Receptor a Mouse Monoclonal Antibody [GM029] Concentrate
Genemed anti-Estrogen Receptor a Rabbit Monoclonal Antibody [EP1], Concentrate
Genemed anti-Estrogen Receptor a Rabbit Monoclonal Antibody [EP1], Ready-To-Use
Genemed anti-Estrogen Receptor a Rabbit Monoclonal Antibody [GR001], Concentrate
Genemed anti-Estrogen Receptor a Rabbit Monoclonal Antibody [GR001], Ready-To-Use
Genemed anti-GFAP Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-HER2 (c-erbB-2) Rabbit Monoclonal Antibody [GR011]. Concentrate
Genemed anti-HER2 (c-erbB-2) Rabbit Monoclonal Antibody [GR011], Ready-To-Use
Genemed anti-Human Chorionic Gonadotropin (hCG) Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-Human Kappa Light Chain Mouse Monoclonal Antibody [HP6053], Ready-To-Use
Genemed anti-Human Lambda Light Chain Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-Insulin Mouse Monoclonal Antibody [2D11-H5], Ready-To-Use
Genemed anti-Ki-67 Mouse Monoclonal Antibody [GM010], Ready-To-Use
Genemed anti-Laminin Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-Lysozyme (Muramidase) Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-Melan-A Mouse Monoclonal Antibody [A103], Ready-To-Use
Genemed anti-Melanosome Mouse Monoclonal Antibody [HMB45], Ready-To-Use
Genemed anti-MLH1 Mouse Monoclonal Antibody [GM011], Ready-To-Use
Genemed anti-MSH2 Mouse Monoclonal Antibody [FE11], Concentrate
Genemed anti-MSH2 Mouse Monoclonal Antibody [FE11], Ready-To-Use
Genemed anti-MSH6 Mouse Monoclonal Antibody [GM024], Ready-To-Use
Genemed anti-MUCSAC Mouse Monoclonal Antibody [Nd-2], Ready-To-Use
Genemed anti-Muscle Actin Mouse Monoclonal Antibody [HHF35], Ready-To-Use
Genemed anti-MyoD1 Mouse Monoclonal Antibody [5.8A], Ready-To-Use
Genemed anti-MyoD1 Mouse Monoclonal Antibody [F5D], Ready-To-Use
Genemed anti-Neurofilaments Mouse Monoclonal Antibody [2F11], Ready-To-Use
Genemed anti-p53 Mouse Monoclonal Antibody [BP-53-12], Ready-To-Use
Genemed anti-p63 Mouse Monoclonal Antibody [4B1E12], Concentrate
Genemed anti-p63 Mouse Monoclonal Antibody [4B1E12], Ready-To-Use
Genemed anti-PAX5 Rabbit Monoclonal Antibody [GR024], Ready-To-Use
Genemed anti-PCNA Mouse Monoclonal Antibody [PC10], Ready-To-Use
Genemed anti-PLAP Mouse Monoclonal Antibody [GM022], Ready-To-Use
Genemed anti-Podoplanin Mouse Monoclonal Antibody [D2-40], Ready-To-Use
Genemed anti-Progesterone Receptor Rabbit Monoclonal Antibody [Y85], Concentrate
Genemed anti-Progesterone Receptor Rabbit Monoclonal Antibody [Y85], Ready-To-Use
Genemed anti-Prostate Specific Antigen Rabbit Polyclonal Antibody, Concentrate
Genemed anti-Prostate Specific Antigen Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-PsAP (PAP) Mouse Monoclonal Antibody [PASE/4LJ], Ready-To-Use
Genemed anti-S100 Rabbit Polyclonal Antibody, Concentrate
Genemed anti-S100 Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-Smooth Muscle Actin Mouse Monoclonal Antibody [1A4], Ready-To-Use
Genemed anti-Synaptophysin Rabbit Monoclonal Antibody [GR007], Ready-To-Use
Genemed anti-TdT Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-Thyroglobulin Mouse Monoclonal Antibody [2H11/6E1], Ready-To-Use
Genemed anti-Thyroid Transcription Factor-1 Mouse Monoclonal Antibody [8G7G3/1], Ready-To-Use
Genemed anti-Villin Rabbit Monoclonal Antibody [GR016], Ready-To-Use
Genemed anti-Vimentin Mouse Monoclonal Antibody [V9], Ready-To-Use
Genemed anti-Von Willebrand Factor (Factor VIII RA) Rabbit Polyclonal Antibody, Ready-To-Use
Genemed anti-WT1 Mouse Monoclonal Antibody [6F-H2], Concentrate
Genemed anti-WT1 Mouse Monoclonal Antibody [6F-H2], Ready-To-Use





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Genemed Non-immune Mouse Ig Antibody Negative Control, Ready-To-Use
Genemed Non-immune Rabbit Ig Antibody Negative Control, Ready-To-Use
Tissue-Tek Genie® anti-BOB,1 Mouse Monoclonal Antibody
Tissue-Tek Genie® anti-CD61 Mouse Monoclonal Antibody [ZM33]
Tissue-Tek Genie® anti-OCT2 Rabbit Monoclonal Antibody [EP284]
Tissue-Tek Genie® anti-Perforin Mouse Monoclonal Antibody [5B10]
Tissue-Tek Genie® anti-Prostein Rabbit Monoclonal Antibody [ZR9]
Tissue-Tek Genie® anti-SOX11 Mouse Monoclonal Antibody [GM032]
Tissue-Tek Genie® DUO anti-Pan Cytokeratin [AE1/AE3/DC10] / CD31[RM247] Antibody Cocktail
Tissue-Tek Genie® DUO anti-AMACR [13H4] / p63 [MX013] / CK5/6 [D5/16B4] PIN Antibody Cocktail
Tissue-Tek Genie® anti-Actin, Smooth Muscle Mouse Monoclonal Antibody [1A4], Ready-To-Use
Tissue-Tek Genie® anti-AMACR Rabbit Monoclonal Antibody [13H4], Ready-To-Use
Tissue-Tek Genie® anti-BCL2 Rabbit Monoclonal Antibody [EP36], Ready-To-Use
Tissue-Tek Genie® anti-BCL6 Rabbit Monoclonal Antibody [EP278], Ready-To-Use
Tissue-Tek Genie® anti-beta-Catenin Rabbit Monoclonal Antibody [EP35], Ready-To-Use
Tissue-Tek Genie® anti-Calponin Rabbit Monoclonal Antibody [EP63], Ready-To-Use
Tissue-Tek Genie® anti-Calretinin Rabbit Polyclonal Antibody, Ready-To-Use
Tissue-Tek Genie® anti-CD10 Mouse Monoclonal Antibody [GM003], Ready-To-Use
Tissue-Tek Genie® anti-CD117 (c-kit) Rabbit Monoclonal Antibody [EP10], Ready-To-Use
Tissue-Tek Genie® anti-CD138 Mouse Monoclonal Antibody [B-A38], Ready-To-Use
Tissue-Tek Genie® anti-CD15 Rabbit Monoclonal Antibody [EP273], Ready-To-Use
Tissue-Tek Genie® anti-CD163 Rabbit Monoclonal Antibody [EP324], Ready-To-Use
Tissue-Tek Genie® anti-CD1a Rabbit Monoclonal Antibody [EP80], Ready-To-Use
Tissue-Tek Genie® anti-CD2 Rabbit Monoclonal Antibody [EP222], Ready-To-Use
Tissue-Tek Genie® anti-CD20 Mouse Monoclonal Antibody [L26], Ready-To-Use
Tissue-Tek Genie® anti-CD21 Rabbit Monoclonal Antibody [EP64], Ready-To-Use
Tissue-Tek Genie® anti-CD23 Rabbit Monoclonal Antibody [GR013], Ready-To-Use
Tissue-Tek Genie® anti-CD3 Rabbit Monoclonal Antibody [EP177], Ready-To-Use
Tissue-Tek Genie® anti-CD3 Mouse Monoclonal Antibody [ZM45]
Tissue-Tek Genie® anti-CD30 Mouse Monoclonal Antibody [Ber-H2], Ready-To-Use
Tissue-Tek Genie® anti-CD31 Rabbit Monoclonal Antibody [RM247], Ready-To-Use
Tissue-Tek Genie® anti-CD34 Mouse Monoclonal Antibody [QBEnd/10], Ready-To-Use
Tissue-Tek Genie® anti-CD38 Mouse Monoclonal Antibody [GM038], Ready-To-Use
Tissue-Tek Genie® anti-CD4 Rabbit Monoclonal Antibody [EP204], Ready-To-Use
Tissue-Tek Genie® anti-CD43 Mouse Monoclonal Antibody [DF-T1], Ready-To-Use
Tissue-Tek Genie® anti-CD45 Rabbit Monoclonal Antibody [GR009], Ready-To-Use
Tissue-Tek Genie® anti-CD5 Rabbit Monoclonal Antibody [GR020], Ready-To-Use
Tissue-Tek Genie® anti-CD56 Rabbit Monoclonal Antibody [MRQ-42], Ready-To-Use
Tissue-Tek Genie® anti-CD63 Rabbit Monoclonal Antibody [EP211], Ready-To-Use
Tissue-Tek Genie® anti-CD68 Rabbit Monoclonal Antibody [GR021], Ready-To-Use
Tissue-Tek Genie® anti-CD7 Rabbit Monoclonal Antibody [EP132], Ready-To-Use
Tissue-Tek Genie® anti-CD79a Rabbit Monoclonal Antibody [GR019], Ready-To-Use
Tissue-Tek Genie® anti-CD8 Mouse Monoclonal Antibody [C8/144B], Ready-To-Use
Tissue-Tek Genie® anti-CDX2 Rabbit Monoclonal Antibody [EP25], Ready-To-Use
Tissue-Tek Genie® anti-CEA Mouse Monoclonal Antibody [COL-1], Ready-To-Use
Tissue-Tek Genie® anti-Chromogranin A Mouse Monoclonal Antibody [LK2H10], Ready-To-Use
Tissue-Tek Genie® anti-Cyclin D1 Rabbit Monoclonal Antibody [EP12], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin 14 Mouse Monoclonal Antibody [LL002], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin 18 Mouse Monoclonal Antibody [DC10], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin 19 Mouse Monoclonal Antibody [A53-B/A2.26], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin 20 Mouse Monoclonal Antibody [Ks20.8], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin 5/6 Mouse Monoclonal Antibody [D5/16 B4], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin 7 Mouse Monoclonal Antibody [OV-TL 12/30], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin HMW (CK5) Mouse Monoclonal Antibody [GM028], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin HMW Mouse Monoclonal Antibody [34bE12], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin LMW (CK8) Rabbit Monoclonal Antibody [EP17], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin LMW (CK8/18) Antibody Cocktail [EP17/DC10], Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin Mouse Antibody Cocktail [AE1/AE3], Ready-To-Use





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Tissue-Tek Genie® anti-Cytokeratin Pan Antibody Cocktail [AE1/AE3/DC10], Ready-To-Use
Tissue-Tek Genie® anti-Desmin Mouse Monoclonal Antibody [GM007], Ready-To-Use
Tissue-Tek Genie® anti-DOG1 Mouse Monoclonal Antibody [DOG1.1], Ready-To-Use
Tissue-Tek Genie® anti-E-Cadherin Mouse Monoclonal Antibody [GM016], Ready-To-Use
Tissue-Tek Genie® anti-Epithelial Cell Adhesion Molecule Mouse Monoclonal Antibody [VU-1D9], Ready-To-Use
Tissue-Tek Genie® anti-Epithelial Membrane Antigen Mouse Monoclonal Antibody [E29], Ready-To-Use
Tissue-Tek Genie® anti-Factor XIIIa Rabbit Monoclonal Antibody [EP292], Ready-To-Use
Tissue-Tek Genie® anti-Gastrin Rabbit Polyclonal Antibody, Ready-To-Use
Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [EP368], Ready-To-Use
Tissue-Tek Genie® anti-Glial Fibrillary Acidic Protein (GFAP) Mouse Monoclonal Antibody [GA-5], Ready-To-Use
Tissue-Tek Genie® anti-Helicobacter Pylori Rabbit Monoclonal Antibody [EP279], Ready-To-Use
Tissue-Tek Genie® anti-HHV-8 Mouse Monoclonal Antibody [13B10], Ready-To-Use
Tissue-Tek Genie® anti-IgA Rabbit Monoclonal Antibody [EP170], Ready-To-Use
Tissue-Tek Genie® anti-IgD Rabbit Monoclonal Antibody [EP173], Ready-To-Use
Tissue-Tek Genie® anti-IgG Rabbit Monoclonal Antibody [RM116], Ready-To-Use
Tissue-Tek Genie® anti-IgM Rabbit Polyclonal Antibody, Ready-To-Use
Tissue-Tek Genie® anti-Kappa Light Chains Rabbit Polyclonal Antibody, Ready-To-Use
Tissue-Tek Genie® anti-Ki67 Mouse Monoclonal Antibody [GM010], Ready-To-Use
Tissue-Tek Genie® anti-Lambda Light Chains Rabbit Polyclonal Antibody, Ready-To-Use
Tissue-Tek Genie® anti-Melan A Rabbit Monoclonal Antibody [EP43], Ready-To-Use
Tissue-Tek Genie® anti-Melanoma Pan Antibody Cocktail [HMB45/EP43/T311], Ready-To-Use
Tissue-Tek Genie® anti-Melanosome Mouse Monoclonal Antibody [HMB45], Ready-To-Use
Tissue-Tek Genie® anti-MLH1 Mouse Monoclonal Antibody [GM011], Ready-To-Use
Tissue-Tek Genie® anti-MSH2 Rabbit Monoclonal Antibody [RED2], Ready-To-Use
Tissue-Tek Genie® anti-MSH6 Rabbit Monoclonal Antibody [EP49], Ready-To-Use
Tissue-Tek Genie® anti-MUM1 Rabbit Monoclonal Antibody [EP190], Ready-To-Use
Tissue-Tek Genie® anti-Myeloperoxidase (MPO) Rabbit Monoclonal Antibody [EP151], Ready-To-Use
Tissue-Tek Genie® anti-Napsin A Rabbit Monoclonal Antibody [EP205], Ready-To-Use
Tissue-Tek Genie® anti-Neurofilament Mouse Monoclonal Antibody [2F11], Ready-To-Use
Tissue-Tek Genie® anti-Neuron Specific Enolase Rabbit Monoclonal Antibody [EP319], Ready-To-Use
Tissue-Tek Genie® anti-p16 Mouse Monoclonal Antibody [MX007], Ready-To-Use
Tissue-Tek Genie® anti-p53 Mouse Monoclonal Antibody [BP53.12], Ready-To-Use
Tissue-Tek Genie® anti-p63 Mouse Monoclonal Antibody [MX013], Ready-To-Use
Tissue-Tek Genie® anti-PAX5 Rabbit Monoclonal Antibody [EP156], Ready-To-Use
Tissue-Tek Genie® anti-PAX8 Rabbit Monoclonal Antibody [EP298], Ready-To-Use
Tissue-Tek Genie® anti-Placental Alkaline Phosphatase Mouse Monoclonal Antibody [GM022], Ready-To-Use
Tissue-Tek Genie® anti-PMS2 Rabbit Monoclonal Antibody [EP51], Ready-To-Use
Tissue-Tek Genie® anti-Podoplanin Mouse Monoclonal Antibody [D2-40], Ready-To-Use
Tissue-Tek Genie® anti-S100B Rabbit Monoclonal Antibody [EP32], RTU, 250 tests, 1 cartridge; 1 unit, RTU
Tissue-Tek Genie® anti-SOX10 Rabbit Monoclonal Antibody [EP268], Ready-To-Use
Tissue-Tek Genie® anti-Synaptophysin Mouse Monoclonal Antibody [BS15], Ready-To-Use
Tissue-Tek Genie® anti-Terminal Deoxynucleotidyl Transferase Mouse Monoclonal Antibody [SEN28], RTU
Tissue-Tek Genie® anti-Thyroid Transcription Factor-1 Rabbit Monoclonal Antibody [EP229], Ready-To-Use
Tissue-Tek Genie® anti-Trypsin Rabbit Monoclonal Antibody [EP259], Ready-To-Use
Tissue-Tek Genie® anti-Vimentin Mouse Monoclonal Antibody [V9], Ready-To-Use
Tissue-Tek Genie® anti-WT1 Rabbit Monoclonal Antibody [EP122], Ready-To-Use
Tissue-Tek Genie® anti-PD-1 Rabbit Monoclonal Antibody [EP239], Ready-To-Use
Tissue-Tek Genie® anti-CD57 Mouse Monoclonal Antibody [NK1], Ready-To-Use
Tissue-Tek Genie® anti-ALK (Heme) Mouse Monoclonal Antibody [1A4], Ready-To-Use
Tissue-Tek Genie® anti-IgG 4 Mouse Monoclonal Antibody, [HP6025], Ready-To-Use
Tissue-Tek Genie® CISH Kappa Probe RTU, 10 capsules
Tissue-Tek Genie® CISH EBER Probe RTU, 10 capsules
Tissue-Tek Genie® CISH Negative Control RTU, 10 capsules
Tissue-Tek Genie® CISH Positive Control RTU, 10 capsules
Tissue-Tek Genie® FITC anti-C3 Goat Polyclonal Antibody, Ready-To-Use
Tissue-Tek Genie® FITC anti-Fibrinogen Goat Polyclonal Antibody, Ready-To-Use
Tissue-Tek Genie® FITC anti-IgA Goat Polyclonal Antibody, Ready-To-Use
Tissue-Tek Genie® FITC anti-IgG Goat Polyclonal Antibody, Ready-To-Use





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Tissue-Tek Genie® FITC anti-IgM Goat Polyclonal Antibody, Ready-To-Use
Tissue-Tek Genie® Non-Immune Mouse Ig Antibody, Negative Control, Ready-To-Use
Tissue-Tek Genie® Non-Immune Rabbit Ig Antibody, Negative Control, Ready-To-Use
Tissue-Tek Genie® anti-Cytokeratin 7/19 Antibody Cocktail [OV-TL 12/30 / A53- B/A2.26]
Tissue-Tek Genie® DUO anti-Cytokeratin 5/6 [D5/16B4] / TTF-1 [EP229] Antibody Cocktail
Tissue-Tek Genie® anti-CD1a Mouse Monoclonal Antibody [O10]

Detection Reagents

Genemed Power-Stain™ 1.0 Double Stain (Poly HRP for Mouse + Poly AP for Rabbit). Ready-To-Use
Genemed Power-Stain™ 1.0 Kit Poly HRP AEC Kit for Mouse + Rabbit, Ready-To-Use
Genemed Power-Stain™ 1.0 Kit Poly HRP DAB for Mouse + Rabbit, Ready-To-Use
Genemed Power-Stain™ 1.0 Poly AP for Mouse and Rabbit, Ready-To-Use
Genemed Power-Stain™ 2.0 Poly HRP Kit for Mouse + Rabbit 100mL Ready-To-Use
Tissue-Tek Genie® Pro AP Red Detection Kit, 250 tests, 4 cartridges, Ready-To-Use
Tissue-Tek Genie® Pro Detection Kit, DAB: 250 tests, 6 cartridges, Ready-To-Use
Tissue-Tek Genie® Installation Kit. Ready -To-Use
Tissue-Tek Genie® Starter Kit, U.S.A.: Ready-To-Use
Tissue-Tek Genie® DAB Cleaning Reagent Kit
Tissue-Tek Genie® DAB Cleaning Consumables Kit

Bulk and Ancillary Reagents

Genemed A/B Block Kit (Avidin/Biotin Blocking Solution) Ready-To Use
Genemed AEC Substrate, Ready-To-Use
Genemed Antibody Diluent for Automated Stainers, Ready-To-Use
Genemed Blocking Solution (Non-immune), Ready-To-Use
Genemed C-Block (Casein Blocking Solution), Ready-To-Use
Genemed Citrate Buffer pH 6 (20X), Concentrate
Genemed Citrate Buffer pH 6, Ready-To-Use
Genemed CleanMount™ Aqueous Mounting Solution, Ready-To-Use
Genemed GVA Aqueous Mounting Solution, Ready-To-Use
Genemed Mayer's Hematoxylin, Ready-To-Use
Genemed Mini PAP Pen
Genemed PBS Powder, 2 pouches
Genemed Primary Antibody Diluent, Ready-To-Use
Genemed Proteinase K, Ready-To-Use
Genemed Sensitive DAB Substrate Kit, Ready-To-Use
Genemed SSC Buffer (20X), Concentrate
Genemed Super PAP Pen
Genemed TBST (Tris Buffered Saline and 0.05% Tween 20), pH 7.4 (20X), Concentrate
Genemed Tris EDTA Buffer pH 9 (20X), Concentrate
Genemed Tris EDTA Buffer pH 9, Ready-To-Use
Genemed® CISH Amplification Linker RTU, 1 bottle, mL
Genemed® SSC Stringent Wash Buffer RTU, 1 bottle, 3.8L
Genemed® CISH Kappa Probe RTU, 1 bottle, 15mL
Genemed® CISH Lambda Probe RTU, 1 bottle, 15 mL
Genemed® CISH EBER Probe RTU, 1 bottle, 15 mL
Genemed® CISH Positive Control RTU, 1 bottle, 15 mL
Genemed® CISH Negative Control RTU, 1 bottle, 15 mL
Tissue-Tek Genie® CISH Amplifier RTU, 100 test, 1 cartridge
Tissue-Tek Genie® SSC Stringent Wash Buffer, RTU, 1 bottle, 3.8L
Tissue-Tek Genie® Proteinase K RTU, 100 test, 1 cartridge, 1; unit
Tissue-Tek Genie® User-Fillable Cartridge for CISH Amplification Linker, 6 cartridges
Tissue-Tek Genie® Antibody Diluent, 100 mL, Ready-To-Use
Tissue-Tek Genie® Citrate Antigen Retrieval Solution, 3.8 L, Ready-To-Use
Tissue-Tek Genie® Dewax Solution, 3.8 L, Ready-To-Use
Tissue-Tek Genie® Hematoxylin, 250 tests, 1 cartridge, Ready-To-Use
Tissue-Tek Genie® High pH Antigen Retrieval Solution, 3.8 L, Ready-To-Use
Tissue-Tek Genie® RDA-Tag Label Kit, 1 ribbon and 2 rolls for 2,400 RDA-Tag labels





**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. 5130-2-2023

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Tissue-Tek Genie® Reagent Dispense Area [RDA], 90/box
Tissue-Tek Genie® Reagent Dispense Area Tag [RDA-Tag], 90/box
Tissue-Tek Genie® Slide Label Kit, 1 ribbon and 3 rolls for 3,000 slide labels
Tissue-Tek Genie® Storage and Transport Tray
Tissue-Tek Genie® User-Fillable Capsule Sealer
Tissue-Tek Genie® User-Fillable Capsule Sealing System
Tissue-Tek Genie® User-Fillable Capsule Seals, 50/pack
Tissue-Tek Genie® User-Fillable Capsule Tray, 2/box
Tissue-Tek Genie® User-Fillable Capsules, 5D/pack
Tissue-Tek Genie® User-Fillable Cartridge for Biomarker-Binding Reagent, 6 cartridges/box
Tissue-Tek Genie® User-Fillable Cartridge for Enzyme, 6 cartridges/box
Tissue-Tek Genie® Wash Solution, 3.8L. Ready-To-Use
Tissue-Tek Genie® Workflow Organizer

END OF PRODUCT LIST

