



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

**Certificate No. 5957-2-2019**

**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

(Nine 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.

CAPT Sean M. Boyd, MPH, USPHS  
Deputy Director for Regulatory Affairs  
Office of Compliance  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration, DHHS

**This certificate is valid from March 01, 2019 to February 28, 2021.**







**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](http://www.fda.gov)

**Certificate No. 5957-2-2019**

**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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**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

**Name of Product(s)**

**GROSSING AND TRIMMING**

**Instruments**

Tissue-Tek® Accu-Edge® 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

**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® 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

**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







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Tissue-Tek VIP® Paraffin

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

Tissue-Tek Xpress® x50 Processing Reagent Set

Tissue-Tek Xpress® x120 Processing Reagent Set

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**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

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**MICROTOMY AND CRYOTOMY**

**Instruments**

Tissue-Tek AutoSection® Automated Microtome

Tissue-Tek® Cryo3® Flex Cryostat

Accu-Cut® SRM™ 200 Manual Rotary Microtomes

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® Accu-Edge® Microtome Blade System

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

Tissue-Tek® O.C.T Compound

Cryomold®

Specimen Holders

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**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

Histo-Tek® SL Slide Stainer

Tissue-Tek® DRS 2000®

**Consumables**

Tissue-Tek® Manual Slide Staining Kit

Tissue-Tek® Coverslipping Film 60 m







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Tissue-Tek® Glas™ g2 Coverslips and Easy Holder

Tissue-Tek® Glas™ Mounting Medium

**CYTOCENTRIFUGATION**

**Instruments**

Cyto-Tek® Cytology Centrifuge

Cyto-Tek® 2500 Cytocentrifuge

**Consumables**

Fluid Chambers

**DIGITAL IMAGING**

**Instruments**

VisionTek® Digital Microscope

VisionTek® M6 Digital Microscope

**IMMUNOHISTOCHEMISTRY (IHC)**

**Primary Antibodies**

Genemed anti-Actin, Smooth Muscle Mouse Monoclonal Antibody [1A4] Concentrate

Genemed anti-AFP Rabbit Polyclonal Antibody, Concentrate

Genemed anti-AFP Rabbit Polyclonal Antibody, Ready-To-Use

Genemed anti-AMACR Rabbit Monoclonal Antibody [13H4], Concentrate

Genemed anti-AMACR Rabbit Monoclonal Antibody [13H4], Ready-To-Use

Genemed anti-Bcl-2 Mouse Monoclonal Antibody [Bcl-2-100], Concentrate

Genemed anti-Bcl-2 Mouse Monoclonal Antibody [Bcl-2-100], Ready-To-Use

Genemed anti-CA19-9 (Sialyl Lewis) Mouse Monoclonal Antibody [SPan-1], Concentrate

Genemed anti-CA19-9 (Sialyl Lewis) Mouse Monoclonal Antibody [SPan-1], Ready-To-Use

Genemed anti-Calponin Mouse Monoclonal Antibody [CALP], Concentrate

Genemed anti-Calponin Mouse Monoclonal Antibody [CALP], Ready-To-Use

Genemed anti-Calretinin Rabbit Polyclonal Antibody, Concentrate

Genemed anti-Calretinin Rabbit Polyclonal Antibody, Ready-To-Use

Genemed anti-CD10 Mouse Monoclonal Antibody [GM003], Concentrate

Genemed anti-CD10 Mouse Monoclonal Antibody [GM003], Ready-To-Use

Genemed anti-CD19 Rabbit Monoclonal Antibody [GR014], Concentrate

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], Concentrate

Genemed anti-CD23 Rabbit Monoclonal Antibody [GR013], Ready-To-Use

Genemed anti-CD3 Rabbit Polyclonal Antibody, Concentrate

Genemed anti-CD3 Rabbit Polyclonal Antibody, Ready-To-Use

Genemed anti-CD30 Mouse Monoclonal Antibody [Ber-H2], Concentrate

Genemed anti-CD30 Mouse Monoclonal Antibody [Ber-H2], Ready-To-Use

Genemed anti-CD30 Rabbit Polyclonal Antibody, Concentrate

Genemed anti-CD30 Rabbit Polyclonal Antibody, Ready-To-Use

Genemed anti-CD31 (PECAM-1) Mouse Monoclonal Antibody [GM006], Concentrate

Genemed anti-CD31 (PECAM-1) Mouse Monoclonal Antibody [GM006], Ready-To-Use

Genemed anti-CD34 Mouse Monoclonal Antibody [QBend10], Concentrate

Genemed anti-CD34 Mouse Monoclonal Antibody [QBend10], Ready-To-Use

Genemed anti-CD45 (LCA) Rabbit Monoclonal Antibody [GR009], Concentrate

Genemed anti-CD45 (LCA) Rabbit Monoclonal Antibody [GR009], Ready-To-Use

Genemed anti-CD45RO Mouse Monoclonal Antibody [UCHL-1], Concentrate

Genemed anti-CD45RO Mouse Monoclonal Antibody [UCHL-1], Ready-To-Use

Genemed anti-CD5 Rabbit Monoclonal Antibody [GR020] Concentrate

Genemed anti-CD5 Rabbit Monoclonal Antibody [GR020], Ready-To-Use

Genemed anti-CD56 (NCAM) Mouse Monoclonal Antibody [123C3], Concentrate

Genemed anti-CD56 (NCAM) Mouse Monoclonal Antibody [123C3], Ready-To-Use

Genemed anti-CD68 Rabbit Monoclonal Antibody [GR021] Concentrate

Genemed anti-CD68 Rabbit Monoclonal Antibody [GR021], Ready-To-Use







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Genemed anti-CD79a Rabbit Monoclonal Antibody [GR019] Concentrate  
Genemed anti-CD79a Rabbit Monoclonal Antibody [GR019], Ready-To-Use  
Genemed anti-CD8 Mouse Monoclonal Antibody [C8/144B], Concentrate  
Genemed anti-CD8 Mouse Monoclonal Antibody [C8/144B], Ready-To-Use  
Genemed anti-CDX2 Rabbit Monoclonal Antibody [GR023] Concentrate  
Genemed anti-CDX2 Rabbit Monoclonal Antibody [GR023], Ready-To-Use  
Genemed anti-CEA Mouse Monoclonal Antibody [COL-1], Concentrate  
Genemed anti-CEA Mouse Monoclonal Antibody [COL-1], Ready-To-Use  
Genemed anti-Chromogranin A Rabbit Polyclonal Antibody, Concentrate  
Genemed anti-Chromogranin A Rabbit Polyclonal Antibody, Ready-To-Use  
Genemed anti-c-kit (CD117) Rabbit Polyclonal Antibody, Concentrate  
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], Concentrate  
Genemed anti-Cytokeratin 18 Mouse Monoclonal Antibody [DC-10], Ready-To-Use  
Genemed anti-Cytokeratin 19 Mouse Monoclonal Antibody [A53-B/A2.26], Concentrate  
Genemed anti-Cytokeratin 19 Mouse Monoclonal Antibody [A53-B/A2.26], Ready-To-Use  
Genemed anti-Cytokeratin 20 Mouse Monoclonal Antibody [Ks20.8], Concentrate  
Genemed anti-Cytokeratin 20 Mouse Monoclonal Antibody [Ks20.8], Ready-To-Use  
Genemed anti-Cytokeratin 5 Mouse Monoclonal Antibody [GM028] Concentrate  
Genemed anti-Cytokeratin 5 Mouse Monoclonal Antibody [GM028], Ready-To-Use  
Genemed anti-Cytokeratin 5/6 Mouse Monoclonal Antibody [D5/16B4], Concentrate  
Genemed anti-Cytokeratin 5/6 Mouse Monoclonal Antibody [D5/16B4], Ready-To-Use  
Genemed anti-Cytokeratin 7 Mouse Monoclonal Antibody [OV-TL 12/30], Concentrate  
Genemed anti-Cytokeratin 7 Mouse Monoclonal Antibody [OV-TL 12/30], Ready-To-Use  
Genemed anti-Cytokeratin HMW Mouse Monoclonal Antibody [34bE12], Concentrate  
Genemed anti-Cytokeratin HMW Mouse Monoclonal Antibody [34bE12], Ready-To-Use  
Genemed anti-Cytokeratin Mouse Monoclonal Antibody [AE1], Concentrate  
Genemed anti-Cytokeratin Mouse Monoclonal Antibody [AE1], Ready-To-Use  
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], Concentrate  
Genemed anti-Desmin Mouse Monoclonal Antibody [GM007], Ready-To-Use  
Genemed anti-E-Cadherin Mouse Monoclonal Antibody [GM016], Concentrate  
Genemed anti-E-Cadherin Mouse Monoclonal Antibody [GM016], 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], Concentrate  
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-1D9], Ready-To-Use  
Genemed anti-Estrogen Receptor  $\alpha$  Mouse Monoclonal Antibody [GM029] Concentrate  
Genemed anti-Estrogen Receptor  $\alpha$  Mouse Monoclonal Antibody [GM029], Ready-To-Use  
Genemed anti-Estrogen Receptor  $\alpha$  Rabbit Monoclonal Antibody [EP1], Concentrate  
Genemed anti-Estrogen Receptor  $\alpha$  Rabbit Monoclonal Antibody [EP1], Ready-To-Use  
Genemed anti-Estrogen Receptor  $\alpha$  Rabbit Monoclonal Antibody [GR001], Concentrate  
Genemed anti-Estrogen Receptor  $\alpha$  Rabbit Monoclonal Antibody [GR001], Ready-To-Use  
Genemed anti-Galectin-3 Mouse Monoclonal Antibody [9C4], Concentrate  
Genemed anti-Galectin-3 Mouse Monoclonal Antibody [9C4], Ready-To-Use  
Genemed anti-GFAP Rabbit Polyclonal Antibody, Concentrate  
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, Concentrate  
Genemed anti-Human Chorionic Gonadotropin (hCG) Rabbit Polyclonal Antibody, Ready-To-Use  
Genemed anti-Human Kappa Light Chain Mouse Monoclonal Antibody [HP6053], Concentrate  
Genemed anti-Human Kappa Light Chain Mouse Monoclonal Antibody [HP6053], Ready-To-Use







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Genemed anti-Human Kappa Light Chain Rabbit Polyclonal Antibody, Concentrate  
Genemed anti-Human Lambda Light Chain Mouse Monoclonal Antibody [HP6054], Concentrate  
Genemed anti-Human Lambda Light Chain Mouse Monoclonal Antibody [HP6054], Ready-To-Use  
Genemed anti-Human Lambda Light Chain Rabbit Polyclonal Antibody, Concentrate  
Genemed anti-Human Lambda Light Chain Rabbit Polyclonal Antibody, Ready-To-Use  
Genemed anti-Insulin Mouse Monoclonal Antibody [2D11-H5], Concentrate  
Genemed anti-Insulin Mouse Monoclonal Antibody [2D11-H5], Ready-To-Use  
Genemed anti-Ki-67 Mouse Monoclonal Antibody [GM010], Concentrate  
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, Concentrate  
Genemed anti-Lysozyme (Muramidase) Rabbit Polyclonal Antibody, Ready-To-Use  
Genemed anti-Melan-A Mouse Monoclonal Antibody [A103], Concentrate  
Genemed anti-Melan-A Mouse Monoclonal Antibody [A103], Ready-To-Use  
Genemed anti-Melanosome Mouse Monoclonal Antibody [HMB45], Concentrate  
Genemed anti-Melanosome Mouse Monoclonal Antibody [HMB45], Ready-To-Use  
Genemed anti-MLH1 Mouse Monoclonal Antibody [GM011], Concentrate  
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], Concentrate  
Genemed anti-MSH6 Mouse Monoclonal Antibody [GM024], Ready-To-Use  
Genemed anti-MUC5AC Mouse Monoclonal Antibody [Nd-2], Concentrate  
Genemed anti-MUC5AC Mouse Monoclonal Antibody [Nd-2], Ready-To-Use  
Genemed anti-Muscle Actin Mouse Monoclonal Antibody [HHF35], Concentrate  
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 [5.8A], Concentrate  
Genemed anti-Myogenin Mouse Monoclonal Antibody [F5D], Concentrate  
Genemed anti-Myogenin Mouse Monoclonal Antibody [F5D], Ready-To-Use  
Genemed anti-N-Cadherin Mouse Monoclonal Antibody [GM031], Concentrate  
Genemed anti-N-Cadherin Mouse Monoclonal Antibody [GM031], Ready-To-Use  
Genemed anti-Neurofilaments Mouse Monoclonal Antibody [2F11], Concentrate  
Genemed anti-Neurofilaments Mouse Monoclonal Antibody [2F11], Ready-To-Use  
Genemed anti-p53 Mouse Monoclonal Antibody [BP-53-12], Concentrate  
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], Concentrate  
Genemed anti-PAX5 Rabbit Monoclonal Antibody [GR024], Ready-To-Use  
Genemed anti-PCNA Mouse Monoclonal Antibody [IPC10], Concentrate  
Genemed anti-PCNA Mouse Monoclonal Antibody [IPC10], Ready-To-Use  
Genemed anti-PLAP Mouse Monoclonal Antibody [GM022], Concentrate  
Genemed anti-PLAP Mouse Monoclonal Antibody [GM022], Ready-To-Use  
Genemed anti-Podoplanin Mouse Monoclonal Antibody [D2-40], Concentrate  
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], Concentrate  
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], Concentrate  
Genemed anti-Smooth Muscle Actin Mouse Monoclonal Antibody [1A4], Ready-To-Use  
Genemed anti-Synaptophysin Rabbit Monoclonal Antibody [GR007], Concentrate  
Genemed anti-Synaptophysin Rabbit Monoclonal Antibody [GR007], Ready-To-Use







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Genemed anti-TdT Rabbit Polyclonal Antibody, Concentrate  
Genemed anti-TdT Rabbit Polyclonal Antibody, Ready-To-Use  
Genemed anti-Thyroglobulin Mouse Monoclonal Antibody [2H11/6E1], Concentrate  
Genemed anti-Thyroglobulin Mouse Monoclonal Antibody [2H11/6E1], Ready-To-Use  
Genemed anti-Thyroid Transcription Factor-1 Mouse Monoclonal Antibody [8G7G3/1], Concentrate  
Genemed anti-Thyroid Transcription Factor-1 Mouse Monoclonal Antibody [8G7G3/1], Ready-To-Use  
Genemed anti-Villin Rabbit Monoclonal Antibody [GR016], Concentrate  
Genemed anti-Villin Rabbit Monoclonal Antibody [GR016], Ready-To-Use  
Genemed anti-Vimentin Mouse Monoclonal Antibody [V9], Concentrate  
Genemed anti-Vimentin Mouse Monoclonal Antibody [V9], Ready-To-Use  
Genemed anti-Von Willebrand Factor (Factor VIII RA) Rabbit Polyclonal Antibody, Concentrate  
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  
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-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-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







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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  
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-Tryptase 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® 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  
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







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**Detection Reagents**

Genemed Acu-Stain™ HRP Kit for Mouse + Rabbit, Ready-To-Use  
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  
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

**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 Peroxidase Blocking Solution, Ready-To-Use  
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  
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  
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, 50/pack  
Tissue-Tek Genie® User-Fillable Cartridge for Biomarker-Binding Reagent, 6 cartridges/box







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

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)

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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-----

