



**EC Declaration of Conformity  
According to Directive 98/79/EC, Annex III**

**Manufacturer:**

**Sakura Finetek USA, Inc.  
1750 West 214<sup>th</sup> Street  
Torrance, CA 90501  
U.S.A.**

We declare under sole responsibility that the following device, to which this declaration relates, meets the essential health and safety requirements and is in conformity with the relevant sections of applicable EC standards and other normative documents, when it is installed and operated in accordance with the specifications set forth. If changes are made to the products which are covered by this declaration of conformity, the declaration of conformity is no longer valid.

**Device type:** *In Vitro* Diagnostic Medical Device

**Device name:** All Tissue-Tek Genie<sup>®</sup> Biomarker Binding Reagents

**Catalog numbers:** See Appendix 1 (Page 2 – 5)

**Classification** Directive 98/79/EC Annex III applied; U.S.A. Class I

**National and other standards and technical specifications:** EN ISO 18113-2:2009, EN ISO 18113:2009, EN ISO 15223-1:2016, EN ISO 13485:2016, ISO 14971:2019, , 21 CFR 820, EC Directive 98/79/EC

**EU Representative:** Sakura Finetek Europe B.V.  
Flemingweg 10A  
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The Netherlands

**Place of Issue** Torrance, California, U.S.A.

**Signature/Date**  
Manufacturer or  
Responsible Party:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Name/Title of  
Signatory:**

\_\_\_\_\_  
Solmaz M. Shaida

Print Name

\_\_\_\_\_  
Sr. Director of QA/RA

Title

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## Appendix 1

### List of Tissue-Tek Genie® Biomarker Binding Reagents

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Product codes	Product Name
8280-XXXX	Tissue-Tek Genie® anti-CD3 Rabbit Monoclonal Antibody [EP177]
8261-XXXX	Tissue-Tek Genie® anti beta-Catenin Rabbit Monoclonal Antibody [EP35]
8292-XXXX	Tissue-Tek Genie® anti-Actin, Smooth Muscle Mouse Monoclonal Antibody [1A4]
8350-XXXX	Tissue-Tek Genie® anti-ALK (HEME) Mouse Monoclonal Antibody [1A4]
8330-XXXX	Tissue-Tek Genie® anti-ALK (Lung) Mouse Monoclonal Antibody [1A4]
8291-XXXX	Tissue-Tek Genie® anti-AMACR Rabbit Monoclonal Antibody [13H4]
8459-XXXX	Tissue-Tek Genie® anti-BCL2 Rabbit Monoclonal Antibody [EP36]
8461-XXXX	Tissue-Tek Genie® anti-BCL6 Rabbit Monoclonal Antibody [EP278]
8310-XXXX	Tissue-Tek Genie® anti-Calponin Rabbit Monoclonal Antibody [EP63]
8522-XXXX	Tissue-Tek Genie® anti-Calretinin Rabbit Monoclonal Antibody [RM324]
8223-XXXX	Tissue-Tek Genie® anti-Calretinin Rabbit Polyclonal Antibody
8253-XXXX	Tissue-Tek Genie® anti-CD10 Mouse Monoclonal Antibody [GM003]
8267-XXXX	Tissue-Tek Genie® anti-CD117 (c-kit) Rabbit Monoclonal Antibody [EP10]
8503-XXXX	Tissue-Tek Genie® anti-CD13 Rabbit Monoclonal Antibody [EP117]
8241-XXXX	Tissue-Tek Genie® anti-CD138 Mouse Monoclonal Antibody [B-A38]
8321-XXXX	Tissue-Tek Genie® anti-CD14 Rabbit Monoclonal Antibody [EP128]
8256-XXXX	Tissue-Tek Genie® anti-CD15 Mouse Monoclonal Antibody [MMA]
8245-XXXX	Tissue-Tek Genie® anti-CD163 Rabbit Monoclonal Antibody [EP324]
8516-XXXX	Tissue-Tek Genie® anti-CD19 Rabbit Monoclonal Antibody [EP169]
8339-XXXX	Tissue-Tek Genie® anti-CD1a Mouse Monoclonal Antibody [O10]
8246-XXXX	Tissue-Tek Genie® anti-CD1a Rabbit Monoclonal Antibody [EP80]
8255-XXXX	Tissue-Tek Genie® anti-CD2 Rabbit Monoclonal Antibody [EP222]
8259-XXXX	Tissue-Tek Genie® anti-CD20 Mouse Monoclonal Antibody [L26]
8260-XXXX	Tissue-Tek Genie® anti-CD21 Rabbit Monoclonal Antibody [EP64]
8262-XXXX	Tissue-Tek Genie® anti-CD23 Rabbit Monoclonal Antibody [GR013]
8265-XXXX	Tissue-Tek Genie® anti-CD30 Mouse Monoclonal Antibody [Ber-H2]
8282-XXXX	Tissue-Tek Genie® anti-CD31 Rabbit Monoclonal Antibody [RM247]
8268-XXXX	Tissue-Tek Genie® anti-CD34 Mouse Monoclonal Antibody [QBEND10]
8277-XXXX	Tissue-Tek Genie® anti-CD38 Mouse Monoclonal Antibody [GM038]
8226-XXXX	Tissue-Tek Genie® anti-CD4 Rabbit Monoclonal Antibody [EP204]
8279-XXXX	Tissue-Tek Genie® anti-CD43 Mouse Monoclonal Antibody [DF-T1]
8271-XXXX	Tissue-Tek Genie® anti-CD45 Rabbit Monoclonal Antibody [GR009]
8249-XXXX	Tissue-Tek Genie® anti-CD5 Rabbit Monoclonal Antibody [GR020]
8274-XXXX	Tissue-Tek Genie® anti-CD56 Rabbit Monoclonal Antibody [MRQ-42]
8338-XXXX	Tissue-Tek Genie® anti-CD57 Mouse Monoclonal Antibody [NK1]
8518-XXXX	Tissue-Tek Genie® anti-CD61 Mouse Monoclonal Antibody [ZM33]
8283-XXXX	Tissue-Tek Genie® anti-CD63 Rabbit Monoclonal Antibody [EP211]
8275-XXXX	Tissue-Tek Genie® anti-CD68 Rabbit Monoclonal Antibody [GR021]
8251-XXXX	Tissue-Tek Genie® anti-CD7 Rabbit Monoclonal Antibody [EP132]

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Product codes	Product Name
8322-XXXX	Tissue-Tek Genie® anti-CD71 Rabbit Monoclonal Antibody [EP232]
8278-XXXX	Tissue-Tek Genie® anti-CD79a Rabbit Monoclonal Antibody [GR019]
8252-XXXX	Tissue-Tek Genie® anti-CD8 Mouse Monoclonal Antibody [C8/144B]
8281-XXXX	Tissue-Tek Genie® anti-CD99 Rabbit Monoclonal Antibody [EP8]
8285-XXXX	Tissue-Tek Genie® anti-CDX2 Rabbit Monoclonal Antibody [EP25]
8225-XXXX	Tissue-Tek Genie® anti-CEA Mouse Monoclonal Antibody [COL1]
8286-XXXX	Tissue-Tek Genie® anti-Chromogranin A Mouse Monoclonal Antibody [LK2H10]
8332-XXXX	Tissue-Tek Genie® anti-c-Myc Rabbit Monoclonal Antibody [EP121]
8469-XXXX	Tissue-Tek Genie® anti-Cyclin D1 Rabbit Monoclonal Antibody [EP12]
8300-XXXX	Tissue-Tek Genie® anti-Cytokeratin 14 Mouse Monoclonal Antibody [LL002]
8302-XXXX	Tissue-Tek Genie® anti-Cytokeratin 18 Mouse Monoclonal Antibody [DC10]
8303-XXXX	Tissue-Tek Genie® anti-Cytokeratin 19 Mouse Monoclonal Antibody [A53-B/A2.26]
8304-XXXX	Tissue-Tek Genie® anti-Cytokeratin 20 Mouse Monoclonal Antibody [Ks20.8],
8294-XXXX	Tissue-Tek Genie® anti-Cytokeratin 5 Mouse Monoclonal Antibody [GM028]
8408-XXXX	Tissue-Tek Genie® anti-Cytokeratin 5 Rabbit Monoclonal Antibody [RM226]
8295-XXXX	Tissue-Tek Genie® anti-Cytokeratin 5/6 Mouse Monoclonal Antibody [D5/16B4]
8296-XXXX	Tissue-Tek Genie® anti-Cytokeratin 7 Mouse Monoclonal Antibody [OV-TL 12/30]
8297-XXXX	Tissue-Tek Genie® anti-Cytokeratin 7/19 Antibody Cocktail [OV-TL 12/30 / A53- B/A2.26]
8238-XXXX	Tissue-Tek Genie® anti-Cytokeratin 8 Rabbit Monoclonal Antibody [EP17]
8306-XXXX	Tissue-Tek Genie® anti-Cytokeratin HMW Mouse Monoclonal Antibody [34bE12]
8298-XXXX	Tissue-Tek Genie® anti-Cytokeratin LMW (8/18) Antibody Cocktail [EP17/DC-10]
8309-XXXX	Tissue-Tek Genie® anti-Cytokeratin Pan Mouse Monoclonal Antibody [AE1/AE3/DC10]
8311-XXXX	Tissue-Tek Genie® anti-Desmin Mouse Monoclonal Antibody [GM007]
8368-XXXX	Tissue-Tek Genie® anti-DOG1 Mouse Monoclonal Antibody [DOG1.1]
8269-XXXX	Tissue-Tek Genie® anti-E-Cadherin Mouse Monoclonal Antibody [ZM63]
8229-XXXX	Tissue-Tek Genie® anti-E-Cadherin Mouse Monoclonal Antibody [GM016]
8230-XXXX	Tissue-Tek Genie® anti-Epithelial Cell Adhesion Molecule Mouse Monoclonal Antibody [VU-1D9]
8233-XXXX	Tissue-Tek Genie® anti-Epithelial Membrane Antigen Mouse Monoclonal Antibody [E29]
8323-XXXX	Tissue-Tek Genie® anti-ERG Rabbit Monoclonal Antibody [EP111]
8361-XXXX	Tissue-Tek Genie® anti-Estrogen Receptor $\alpha$ Rabbit Monoclonal Antibody [EP1]
8293-XXXX	Tissue-Tek Genie® anti-Factor XIII A Rabbit Monoclonal Antibody [EP292]
8314-XXXX	Tissue-Tek Genie® anti-Gastrin Rabbit Polyclonal Antibody
8242-XXXX	Tissue-Tek Genie® anti-GATA3 Rabbit Monoclonal Antibody [EP368]

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Product codes	Product Name
8325-XXXX	Tissue-Tek Genie® anti-GCDFP-15 Rabbit Monoclonal Antibody [EP95]
8316-XXXX	Tissue-Tek Genie® anti-Glial Fibrillary Acidic Protein (GFAP) Mouse Monoclonal Antibody [GA-5]
8234-XXXX	Tissue-Tek Genie® anti-Granzyme B Rabbit Monoclonal Antibody [EP230]
8317-XXXX	Tissue-Tek Genie® anti-Helicobacter Pylori Rabbit Monoclonal Antibody [EP279]
8374-XXXX	Tissue-Tek Genie® anti-Hepatocyte Specific Antigen (Hep Par 1) Mouse Monoclonal Antibody [OCH1E5]
8362-XXXX	Tissue-Tek Genie® anti-HER2 Rabbit Monoclonal Antibody [GR011]
8365-XXXX	Tissue-Tek Genie® anti-Herpes Simplex Virus 1 (HSV1) Rabbit Polyclonal Antibody
8367-XXXX	Tissue-Tek Genie® anti-Herpes Simplex Virus 2 (HSV2) Rabbit Polyclonal Antibody
8378-XXXX	Tissue-Tek Genie® anti-HHV-8 Mouse Monoclonal Antibody [13B10]
8381-XXXX	Tissue-Tek Genie® anti-IgA Rabbit Monoclonal Antibody [EP170]
8382-XXXX	Tissue-Tek Genie® anti-IgD Rabbit Monoclonal Antibody [EP173]
8383-XXXX	Tissue-Tek Genie® anti-IgG Rabbit Monoclonal Antibody [RM116]
8384-XXXX	Tissue-Tek Genie® anti-IgG4 Mouse Monoclonal Antibody [HP6025]
8385-XXXX	Tissue-Tek Genie® anti-IgM Rabbit Polyclonal Antibody
8394-XXX	Tissue-Tek Genie® anti-Kappa Light Chains Rabbit Polyclonal Antibody
8473-XXXX	Tissue-Tek Genie® anti-Ki67 Mouse Monoclonal Antibody [GM010]
8398-XXXX	Tissue-Tek Genie® anti-Lambda Light Chains Rabbit Polyclonal Antibody
8333-XXXX	Tissue-Tek Genie® anti-Lysozyme Rabbit Polyclonal Antibody
8240-XXXX	Tissue-Tek Genie® anti-Mammaglobin Rabbit Monoclonal Antibody [EP249]
8319-XXXX	Tissue-Tek Genie® anti-Melan A Rabbit Monoclonal Antibody [EP43]
8232-XXXX	Tissue-Tek Genie® anti-Melanosome Mouse Monoclonal Antibody [HMB45]
8324-XXXX	Tissue-Tek Genie® anti-MLH1 Mouse Monoclonal Antibody [GM011]
8327-XXXX	Tissue-Tek Genie® anti-MSH2 Rabbit Monoclonal Antibody [RED2]
8326-XXXX	Tissue-Tek Genie® anti-MSH6 Rabbit Monoclonal Antibody [EP49]
8375-XXXX	Tissue-Tek Genie® anti-MUC1 Mouse Monoclonal Antibody [ZM32]
8329-XXXX	Tissue-Tek Genie® anti-MUM 1 Rabbit Monoclonal Antibody [EP190]
8407-XXXX	Tissue-Tek Genie® anti-Myeloperoxidase (MPO) Rabbit Monoclonal Antibody [EP151]
8517-XXXX	Tissue-Tek Genie® anti-Myosin Smooth Muscle Mouse Monoclonal Antibody [SMMS-1]
8331-XXXX	Tissue-Tek Genie® anti-Napsin A Rabbit Monoclonal Antibody [EP205]
8289-XXXX	Tissue-Tek Genie® anti-Neurofilament Mouse Monoclonal Antibody [2F11]
8447-XXXX	Tissue-Tek Genie® anti-Neuron Specific Enolase Rabbit Monoclonal Antibody [EP319]
8320-XXXX	Tissue-Tek Genie® anti-NKX3-1 Rabbit Monoclonal Antibody [EP356]
8373-XXXX	Tissue-Tek Genie® anti-p120 Rabbit Monoclonal Antibody [EP66]
8313-XXXX	Tissue-Tek Genie® anti-p16 Mouse Monoclonal Antibody [MX007]
8341-XXXX	Tissue-Tek Genie® anti-p40 Mouse Monoclonal Antibody [BC28]

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Product codes	Product Name
8342-XXXX	Tissue-Tek Genie® anti-p40/Myosin Smooth Muscle Mouse Monoclonal Antibody Cocktail [BC28/SMMS-1]
8477-XXXX	Tissue-Tek Genie® anti-p53 Mouse Monoclonal Antibody [BP53.12]
8312-XXXX	Tissue-Tek Genie® anti-p63 Mouse Monoclonal Antibody [MX013]
8371-XXXX	Tissue-Tek Genie® anti-Pan Melanoma Antibody Cocktail [HMB45/EP43/T311]
8500-XXXX	Tissue-Tek Genie® anti-PAX5 Rabbit Monoclonal Antibody [EP156]
8502-XXXX	Tissue-Tek Genie® anti-PAX8 Rabbit Monoclonal Antibody [EP298]
8257-XXXX	Tissue-Tek Genie® anti-PAX8 Rabbit Monoclonal Antibody [RM436]
8287-XXXX	Tissue-Tek Genie® anti-PD1 Rabbit Monoclonal Antibody [EP239]
8263-XXXX	Tissue-Tek Genie® anti-PD-L1 Rabbit Monoclonal Antibody [RM320]
8235-XXXX	Tissue-Tek Genie® anti-Placental Alkaline Phosphatase Mouse Monoclonal Antibody [GM022]
8328-XXXX	Tissue-Tek Genie® anti-PMS2 Rabbit Monoclonal Antibody [EP51]
8515-XXXX	Tissue-Tek Genie® anti-Podoplanin Mouse Monoclonal Antibody [D2-40]
8360-XXXX	Tissue-Tek Genie® anti-Progesterone Receptor Rabbit Monoclonal Antibody [Y85]
8442-XXXX	Tissue-Tek Genie® anti-S100B Rabbit Monoclonal Antibody [EP32]
8258-XXXX	Tissue-Tek Genie® anti-SMAD4 Rabbit Monoclonal Antibody [EP618Y]
8308-XXXX	Tissue-Tek Genie® anti-SOX10 Mouse Monoclonal Antibody [ZM10]
8264-XXXX	Tissue-Tek Genie® anti-SOX10 Rabbit Monoclonal Antibody [EP268]
8521-XXXX	Tissue-Tek Genie® anti-SOX11 Mouse Monoclonal Antibody [GM032]
8228-XXXX	Tissue-Tek Genie® anti-SOX2 Rabbit Monoclonal Antibody [EP103]
8453-XXXX	Tissue-Tek Genie® anti-Synaptophysin Mouse Monoclonal Antibody [BS15]
8406-XXXX	Tissue-Tek Genie® anti-TdT Rabbit Monoclonal Antibody [RM379]
8243-XXXX	Tissue-Tek Genie® anti-Terminal Deoxyribonucleotidyl Transferase Mouse Monoclonal Antibody [SEN28]
8224-XXXX	Tissue-Tek Genie® anti-Thyroid Transcription Factor-1 Rabbit Monoclonal Antibody [EP229]
8254-XXXX	Tissue-Tek Genie® anti-TIA-1 Mouse Monoclonal Antibody [2G9A10F5]
8377-XXXX	Tissue-Tek Genie® anti-Treponema Pallidum Rabbit Polyclonal Antibody
8372-XXXX	Tissue-Tek Genie® anti-Tryptase Rabbit Monoclonal Antibody [EP259]
8336-XXXX	Tissue-Tek Genie® anti-Vimentin Mouse Monoclonal Antibody [V9]
8340-XXXX	Tissue-Tek Genie® anti-WT1 Rabbit Monoclonal Antibody [EP122]
8501-XXXX	Tissue-Tek Genie® anti-ZAP70 Mouse Monoclonal Antibody [ZM97]
9852-XXXX	Tissue-Tek Genie® CISH EBER Probe RTU
9850-XXXX	Tissue-Tek Genie® CISH Kappa Probe RTU
9860-XXXX	Tissue-Tek Genie® CISH mRNA Negative Control Probe RTU
9861-XXXX	Tissue-Tek Genie® CISH mRNA Positive Control Probe RTU
8485-XXXX	Tissue-Tek Genie® DUO anti-AMACR / p63 / CK5/6 PIN-Antibody Cocktail
8486-XXXX	Tissue-Tek Genie® DUO anti-Cytokeratin 5/6 [D5/16B4] / TTF-1 [EP229] Antibody Cocktail



## Appendix 1 List of Tissue-Tek Genie® Biomarker Binding Reagents

Product codes	Product Name
<b>8487-XXXX</b>	Tissue-Tek Genie® DUO anti-p40 [BC28] / Napsin A [EP205] Antibody Cocktail
<b>8481-XXXX</b>	Tissue-Tek Genie® DUO anti-PAN CK [AE1/AE3/DC10] / S100B [EP32] Antibody Cocktail
<b>8539-XXXX</b>	Tissue-Tek Genie® FITC anti-C3 Goat Polyclonal Antibody
<b>8538-XXXX</b>	Tissue-Tek Genie® FITC anti-Fibrinogen Goat Polyclonal Antibody
<b>8536-XXXX</b>	Tissue-Tek Genie® FITC anti-IgA Goat Polyclonal Antibody, 10 Capsules
<b>8535-XXXX</b>	Tissue-Tek Genie® FITC anti-IgG Goat Polyclonal Antibody
<b>8537-XXXX</b>	Tissue-Tek Genie® FITC anti-IgM Goat Polyclonal Antibody
<b>8604-XXXX</b>	Tissue-Tek Genie® Non-immune Mouse Ig Antibody, Negative Control
<b>8605-XXXX</b>	Tissue-Tek Genie® Non-immune Rabbit Ig Antibody, Negative Control
<b>8462-XXXX</b>	Tissue-Tek Genie® anti-BOB.1 Mouse Monoclonal Antibody [ZM74], 10 RTU capsules
<b>8334-XXXX</b>	Tissue-Tek Genie® anti-OCT.2 Rabbit Monoclonal Antibody [EP284]; RTU, 10 capsules/pack
<b>8519-XXXX</b>	Tissue-Tek Genie® anti-Prostein Rabbit Monoclonal Antibody [ZR9], 10 RTU capsules
<b>8480-XXXX</b>	Tissue-Tek Genie® anti-Melan A [EP43] / Ki67 [GM010] Antibody Cocktail, 10 RTU capsules