SAKURA

continuous innovation for pathology

EC Declaration of Conformity
According to IVD Regulation EU 2017/746 Article 17 Annex IV

Manufacturer:

Sakura Finetek USA, Inc.
SRN: US-MF 000022208
1750 West 214th 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changes are made to the products which are covered by this declaration of conformity, the declaration of conformity is no longer valid.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: Tissue-Tek Genie® Ancillary Reagents

Catalog numbers:

Item Code	Description
8742-G001	Tissue-Tek Genie® Citrate Antigen Retrieval Solution; 3.8 L/bottle
8744-G001	Tissue-Tek Genie® High pH Antigen Retrieval Solution; 3.8 L/bottle
8830-M250	Tissue-Tek Genie® Hematoxylin; 250 tests/cartridge
8865-G001	Tissue-Tek Genie® Dewax Solution; 3.8 L/bottle
8866-G004	Tissue-Tek Genie® Pro Antibody Diluent; 4 x 100 mL/bottle
8874-G004	Tissue-Tek Genie® Wash Buffer Solution; 4 x 3.8 L/bottle
9808-M100	Tissue-Tek Genie® CISH Amplifier; 100 tests, 1 cartridge
9810-G001	Tissue-Tek Genie® SSC Stringent Wash Buffer; 3.8 L/bottle
9811-M100	Tissue-Tek Genie® Proteinase K; 100 tests, 1 cartridge

Intended Purpose: Tissue-Tek Genie® Ancillary Reagents are intended for immunohistochemistry (IHC) and chromogenic *in situ* hybridization (CISH) applications in formalin-fixed, paraffin embedded (FFPE) human tissue specimen sections, or immunofluorescent (IF) application in frozen tissue sections, to qualitatively detect target protein(s) or nuclei acid sequence(s) using light/fluorescent microscopy on the automated Tissue-Tek Genie® Advanced Staining System.

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These devices are accessories to an *in vitro* medical device which must be used by a qualified pathologist as an aid to diagnosis to determine the pathological state of a patient.

The clinical interpretation must be made by a qualified pathologist, in conjunction with histological examination, relevant clinical information, other diagnostic tests, and proper controls.

Risk Class of Device:	Class A – Based on Annex VIII (EU 2017/746, rule 5(a))
Basic UDI-DI:	0615238224J6
National and other standards and technical specifications:	ISO 18113-1:2009, EU 2017/746, ISO 13485:2016, ISO 14971:2019, ISO15223-1:2016, ISO/IEC 17050-1:2010, 21 CFR 820
EU Representative:	Sakura Finetek Europe B.V. SRN: NL-AR-000007853 Flemingweg 10A 2408 AV Alphen aan den Rijin The Netherlands
Place of Issue	Torrance, California, U.S.A.
Notified Body/ ID number:	Not Applicable
Additional Information:	Not Applicable

Signature/Date
Manufacturer or Responsible Party:

Digitally signed by Solmaz M. Shaida
DN: cn=Solmaz M. Shaida, o=Sakura Finetek USA, ou=QA/RA department, email=sshaida@sakuraus.com, c=US
Date: 2022.05.19 15:21:47 -07'00'

Signature	Date

Name/Title of Signatory:

Solmaz Shaida	Sr. Dir. of QA/RA
Print Name	Title