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changes are made to the products which are covered by this declaration of conformity, the declaration of conformity is no longer valid.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® Detection Kits

Catalog numbers:

Item Code	Description
8826-K250	Tissue-Tek Genie® Pro Detection Kit, DAB; 250 tests, 6 cartridges; 1 kit
8836-K250	Tissue-Tek Genie® Pro AP Red Detection Kit; 250 tests, 6 cartridges; 1 kit
8837-K250	Tissue-Tek Genie® DUO Mouse-DAB/Rabbit-AP Red Dual Detection Kit; 250 tests, 6 cartridges; 1 kit

Intended Purpose:

Tissue-Tek Genie® Detection Kits are intended for immunohistochemistry (IHC) and chromogenic *in situ* hybridization (CISH) applications in formalin-fixed, paraffin embedded (FFPE) human tissue specimen sections to qualitatively detect target protein(s) or nuclei acid sequence(s) using light microscopy on the automated Tissue-Tek Genie® Advanced Staining System.

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.

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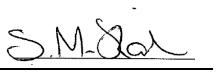
Risk Class of Device:	Class A – Based on Annex VIII (EU 2017/746, rule 5(a))
Basic UDI-DI:	0615233822 5J8
National and other standards and technical specifications:	ISO 18113-1:2009, EU 2017/746, ISO 13485:2016, ISO 14971:2019, ISO 15223-1:2021, ISO/IEC 17050-1:2010, 21 CFR 820
EU Representative:	Sakura 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 15:22:41 -07'00'

Signature	Date

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