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changes are made to the products which are covered by this declaration of conformity, the declaration of conformity is no longer valid.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® Accessories (Auxiliary Products)

Catalog numbers:

Item Code	Description
0008008-01	Tissue-Tek Genie® Controller System
8610-K050	Tissue-Tek Genie® User-Fillable Capsule Sealing System
8616-G090	Tissue-Tek Genie® Reagent Dispense Area [RDA]
8618-G090	Tissue-Tek Genie® Reagent Dispense Area Tag [RDA-Tag]
8619-K100	Tissue-Tek Genie® User-Fillable Capsules and Seals

Intended Purpose:

Tissue-Tek Genie® Accessories (Auxiliary Products) are intended for immunohistochemistry (IHC) and chromogenic in-situ hybridization (CISH) applications in formalin-fixed, paraffin-embedded (FFPE) specimen or frozen tissue sections to qualitatively detect target protein(s) or nucleic acid sequence(s) using light / florescent microscopy on the automated Tissue-Tek Genie® Advanced Staining System.

These auxiliary products will be used in conjugation with Genie reagents including Tissue-Tek Genie® Ancillary Reagents, Detection Reagents, and primary antibodies or probes, which are used in panels as adjunct medical devices for IVD performed by pathologists.

Risk Class of Device: Class *A* – Based on Annex VIII (EU 2017/746, rule 5(a)

Basic UDI-DI: 06152338226JA

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, IEC 62366-1:2020, IEC 61010-1:2010, IEC 61010-2-101:2018

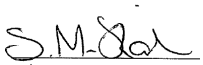
Sakura Finetek USA, Inc.
1750 W 214th Street
Torrance, CA 90501
U.S.A.

Tel. +1 310 972 7800
Fax. +1 310 972 7888

www.sakuraus.com

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 16:54:29 -07'00'

Signature | Date

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

Print Name | Title