SAKURA

continuous innovation for pathology

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

Manufacturer:

Sakura Finetek USA, Inc.
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changes are made to the products which are covered by this declaration of conformity, the declaration of conformity is no longer valid.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:	All Tissue-Tek Genie® Bulk and Ancillary Reagents
Catalog numbers:	See Appendix 1 (Page 2)
Classification	Directive 98/79/EC Annex III applied; U.S.A. Class I
National and other standards and technical specifications:	EN ISO 18113-2:2011, EN ISO 18113:2011, EN ISO 15223-1:2016, EN ISO 13485:2012, EN ISO 14971:2012, , 21 CFR 820, EC Directive 98/79/EC
EU Representative:	Sakura Finetek Europe B.V. Flemingweg 10A 2408 AV Alphen aan den Rijin The Netherlands
Place of Issue	Torrance, California, U.S.A.

Signature/Date
Manufacturer or
Responsible Party:

S. M Shaida
Signature

Dec. 17, 2018
Date

Name/Title of Signatory:

Solmaz M. Shaida
Print Name

Director of QA/RA
Title

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Appendix 1
List of Tissue-Tek Genie® Bulk and Ancillary Reagents

Product codes	Product Name
8865-G001	Tissue-Tek Genie® Dewax Solution
8830-M250	Tissue-Tek Genie® Hematoxylin
8744-G001	Tissue-Tek Genie® High pH Antigen Retrieval Solution
8867-G004	Tissue-Tek Genie® Antibody Diluent
8742-G001	Tissue-Tek Genie® Citrate Antigen Retrieval Solution
8865-G001	Tissue-Tek Genie® Dewax Solution