



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 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changes are made to the products which are covered by this declaration of conformity, the declaration of conformity is no longer valid.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:** Tissue-Tek® AutoSection Automated Microtome

**Catalog number:** 5000

**Intended Purpose:** The Tissue-Tek AutoSection Automated Microtome is a programable motorized microtome, for use with human and animal tissue specimens. The instrument, as part of the histopathology process, is intended to facilitate the in-vitro examination of human and animal tissue for morphology changes by a pathologist.

**Risk Class of Device:** Class A - Based on EU 2017 / 746; Annex VIII, Rule 5 (b)

**Basic UDI-DI:** 06152338229JG

**National and other standards and technical specifications:** IEC 61010-1:2010, IEC 61010-2-101:2018, ISO 18113-1:2009, ISO 18113-3:2009, EU 2017/746, ISO 13485: 2016, ISO 14971: 2019, ISO 15223-1: 2021, EN 13612:2002, ISO/IEC 17050-1:2010, 2011/65/EC, 2014/35/EU, BS/EN/IEC 61326-1:2021 and BS/EN/IEC 61326-2-6:2021, 21 CFR 820.

**EU Representative:** Sakura Finetek Europe B.V.  
SRN: NL-AR-000007853

**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.sakoraus.com](http://www.sakoraus.com)



continuous innovation for pathology

Flemingweg 10A  
2408 AV Alphen aan den Rijn  
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:

  
Signature

May 19, 2022  
Date

**Name/Title of Signatory:**  
Solmaz M. Shaida  
Print Name

Sr. Dir. of QA/RA  
Title