EC Declaration of Conformity
In accordance with EN ISO/IEC 17050-1:2004

We, **Sakura Finetek Europe B.V., Flemingweg 10A, 2408 AV, Alphen aan den Rijn, The Netherlands**

as Authorized Representative herewith declare that:

Equipment: Microtome/Cryostat
Model name/number: Tissue-Tek® Cryo$_3$® Flex / 6203, 6204 and 6205

Manufactured by:

Sakura Finetek USA Inc., 1750 West 214th Street, Torrance, CA 90501, USA

in accordance with the following Directives:

98/79/EC	Conforms with the essential requirements of the In Vitro Diagnostics Directive and its amending directives. Classification: Other (General). Conformity Assessment route: Annex III applied.
2014/30/EU	Conforms with the essential protection requirements of the Electromagnetic Compatibility Directive and its amending directives.
2014/35/EU	Conforms with the safety objectives of the Low Voltage Directive and its amending directives
2011/65/EU	Conforms with the substance restrictions of the Restriction of Hazardous Substances Directive and its amending directives.

Have been designed and manufactured to the relevant parts of the following standards:

EN ISO13485:2016, EN ISO14971:2012, EN 61010-1:2010, EN 61326-1:2013, EN 61010-2-101:2017 and EN 61326-2-6:2013.

In addition the following internal standard applies:

ISO 9001:2015 Quality Management System requirements.

I hereby declare that the equipment named above has been tested and found to comply with the relevant sections of the above referenced specifications. The unit complies with all essential requirements of the Directives.

Signed:

C.Koeman
General Manager

Alphen aan den Rijn, 15 October 2018