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**

Equipment:	IHC and ISH Stainer
Model name/number:	Tissue-Tek® Genie® Advanced Staining System / 8202 consists of: Tissue-Tek® Genie® Advanced Stainer / 8200 Tissue-Tek® Genie® Controller/PC / 008008-01 Tissue-Tek® Genie® Installation kit / 8213 Tissue-Tek® Genie® Starter kit / 8214

Manufactured by:

Sakura Seiki Co. Ltd., 75-5 Imojiya, Chikuma-shi, Nagano-ken, Japan

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 61326-1:2006, EN 61010-1:2001, EN 61010-2-010:2003, EN 61010-2-101:2002, EN ISO 14971:2007 and ISO 13485:2003.

In addition the following internal standard is applied:

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

Chris Koeman

President/General Manager

Alphen aan den Rijn, 5 August 2020