



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: Film Coverslipper
Model name/number: Tissue-Tek Film® Coverslipper/ 4742

Manufactured by:

Sakura Seiki Co. Ltd. Laboratory Unit, 75-5 Imojiya, Chikuma-shi, Nagano-ken 387-0015 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 ISO13485:2016, EN ISO14971:2012, EN 61010-1:2010, EN 61326-1:2013, EN 50581:2012, 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 complies with the relevant sections of the above referenced specifications. The unit complies with all essential requirements of the Directives.

Signed:



President / General Manager

Alphen aan den Rijn



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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: Automated Slide Stainer
Model name/number: Tissue-Tek Prisma® Plus / 6172 and 6173

Manufactured by:

Sakura Seiki Co. Ltd. Laboratory Unit, 75-5 Imojiya, Chikuma-shi, Nagano-ken 387-0015 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
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Signed:



President / General Manager

Alphen aan den Rijn