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: Tissue Processor
Model name/number: Histo-Tek® VP1™ / 1700

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.

has 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: Signed By: Chris Koeman <C.Koeman@sakura.eu>
24/05/2022 14:43:33 CEST
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Sakura Finetek Europe B.V.
SAKURA
Flemingweg 10a - 2408 AV Alphen a/d Rijn
The Netherlands

President / General Manager

Alphen aan den Rijn

Digitally signed by Şarco Alexandru
Date: 2023.11.10 12:58:24 EET
Reason: MoldSign Signature
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