



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: Grossing Tools System
Model name/number: Tissue-Tek® Accu-Edge® Grossing Board / 4800

Manufactured by:

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

in accordance with the following Directive:

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

ISO13485:2016 and ISO14971:2012.

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 Directive.

Signed:


 **C.Koeman**
General Manager

Alphen aan den Rijn, 24 October 2018