



# 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 Legal Manufacturer declare that:

Product: Paraffin Wax  
Product name/number: Tissue-Tek® Paraffin Wax TEK III / 4508, 4509 and 4511

is manufactured 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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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