



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,**

as Legal Manufacturer declare that:

Product: Microtome Blades and Holders
Model name/number: Accu-Edge® Disposable Microtome Blades and Blade Holders
4678, 4679, 4685, 4686, 4687, 4688, 4689, 4690, 4691,
4810, 4980, 7089

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.

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

ISO 13485:2003, ISO 17971:2007 and EN 980:2008

In addition the following internally used standard applies:

ISO 9001:2008 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:

Alphen aan den Rijn,

10 March 2014