

LOT 3



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:

C. Egeerink
General Manager

Alphen aan den Rijn,

10 March 2014



EC Declaration of Conformity

In accordance with EN ISO/IEC 17050-1:2004

We, as Authorized representative:

Sakura Finetek Europe B.V., Flemingweg 10A, 2408 AV, Alphen aan den Rijn

declare that:

Equipment: Grossing, Trimming and dissecting products
Model name/number: Tissue Tek® Accu- Edge®
See Annex I for products

is in accordance with the following Directive:

98/79/EC Conforms with the essential requirements of the In Vitro Directive and its amending directives

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

ISO 13485:2003, ISO 14971:2000, EN 980:2003, ISO 15223:2000, ISO 14644-1:1999.

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 by:



Name: W. Buijteweg
Position: President

Done at: Sakura Finetek Europe B.V.
On: 19/05/2010

CE



EC Declaration of Conformity

In accordance with EN ISO/IEC 17050-1:2004

We, as Authorized representative:

Sakura Finetek Europe B.V., Flemingweg 10A, 2408 AV, Alphen aan den Rijn

declare that:

Equipment: Grossing, Trimming and dissecting products
Model name/number: Tissue Tek[®] Accu- Edge[®]
See Annex I for products

Manufactured for:

Sakura Finetek Europe B.V., Flemingweg 10A, 2408 AV, Alphen aan den Rijn

is in accordance with the following Directive:

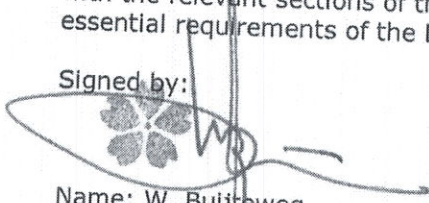
98/79/EC Conforms with the essential requirements of the In Vitro Diagnostics Directive and its amending directives

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

ISO 13485:2003, ISO 14971:2000, EN 980:2003, ISO 15223:2000, ISO 14644-1:1999.

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 by:


Name: W. Buijteweg
Position: President

Done at: Sakura Finetek Europe B.V.
On: 01/04/2011

CE



DECLARATION OF CONFORMITY

Tissue-Tek® Accu-Edge® Disposable Blade Systems

Accu-Edge® for Microtomy/Cryotomy

Product Codes	Accu-Edge® Disposable Blades Quantity
No. 4685	Accu-Edge® High-Profile for large specimens
No. 4980	Accu-Edge® Low-Profile for hard tissues
No. 4810	Accu-Edge® Low-Profile for frozen tissues
No. 4690	Accu-Edge® Low-Profile for hard tissues
No. 4686	Accu-Edge® Low-Profile for ribbon sectioning
No. 4688	Accu-Edge® Low-Profile for extremely thin sectioning
No. 4689	Accu-Edge® Low-Profile for routine sectioning
No. 7089	Accu-Edge® Paraform® Disposable Microtome Blade

Product Codes	Accu-Edge® Blade Holders Quantity
No. 4678	Accu-Edge® Microtome Set 160
No. 4679	Accu-Edge® Microtome Set 240
No. 4680	AO/Reichert Cryostat Holder
No. 4682	Tissue-Tek® II Cryostat Holder with Anti-Roll Plate
No. 4683	Heavy-Duty Holder
No. 4687	The "Original" Accu-Edge® Blade Holder

Accu-Edge® Grossing & Trimming

Product Codes	Tissue-Tek® Accu-Edge® Scalpel Handle and Disposable Blades Quantity
No. 4791	Scalpel Handle
No. 4792	Dissecting Scalpel Blades # 61 Curved tip, 0.6 mm thick
No. 4793	Dissecting Scalpel Blades # 62 Pointed tip, 0.6 mm thick

Product Codes	Tissue-Tek® Accu-Edge® Trimming Knife Handles and Disposable Blades
No. 1454	Plastic Trimming Knife Handle F80
No. 1455	Trimming Knife Handle F80-mini
No. 4785	Trimming Blade 130mm (for use with products 4786, 4787 & 4788)
No. 4786	Trimming Knife Handle/short-straight
No. 4789	Trimming Blades/260mm (for use with product 4790)
No. 4790	Trimming Knife Handle/long-straight

Product Codes	Tissue Tek® Accu-Edge® Replaceable Blade Scissors
No. 4794	Scissors for Replaceable Blade 1 each
No. 4795	Replaceable Blade Scissors; Sharp/Sharp
No. 4796	Replaceable Blade Scissors; Sharp/Blunt
No. 4797	Replaceable Blade Scissors; Blunt/Blunt

Product Codes	Tissue-Tek® Accu-Edge® Semi-disposable Autopsy Knife System
No. 4781	Autopsy Knife Handles
No. 4782	Autopsy Knife Handles/100mm
No. 4783	Autopsy Knife Handles/170mm
No. 4784	Autopsy Brain Knife Blades/325mm