# 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 Authorized Representative herewith declare that:

| | |
|---|---|
| Equipment: | Vacuum Infiltration Processor |
| Model name/number: | Tissue-Tek® VIP® 6 AI / 6042 |

Manufactured by:

**Sakura Seiki Co. Ltd., 75-5 Imojiya, Chikuma-shi, Nagano-ken, 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/EC | 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 61326-1:2006, EN 61010-1:2001, EN 61010-2-010:2003, EN 61010-2-101:2002, EN ISO 14971:2007 and ISO 13485:2003.

In addition the following internal standard is applied:

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.Koeman
General Manager

Alphen aan den Rijn
20-jun-16

EC04/V-01

# 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 Authorized Representative herewith declare that:

| | |
|---|---|
| Equipment: | Vacuum Infiltration Processor |
| Model name/number: | HistoTek® VP1™ / 1700 |

Manufactured by:

**Sakura Seiki Co. Ltd., 75-5 Imojiya, Chikuma-shi, Nagano-ken, 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/EC | Conforms with the substance restrictions of the Restriction of Hazardous Substances Directive and its amending directives. |

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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:

SAKURA

C.Koeman
General Manager

Alphen aan den Rijn
20-jun-16

EC04/V-01

# 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 Authorized Representative herewith declare that:

| | |
|---|---|
| Equipment: | Vacuum Infiltration Processor |
| Model name/number: | Tissue-Tek® VIP® 5 Jr / 5902, 5905 |
| Manufactured by: | |

**Sakura Seiki Co. Ltd., 75-5 Imojiya, Chikuma-shi, Nagano-ken, 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. |
| 2004/108/EC | Conforms with the essential protection requirements of the Electromagnetic Compatibility Directive and its amending directives. |
| 2006/95/EC | Conforms with the safety objectives of the Low Voltage Directive and its amending directives. |

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

EN 61326-1:2006, EN 61010-1:2010, EN 61010-2-010:2003, EN 61010-2-101:2002, EN ISO 14971:2007 and ISO 13485:2003.

In addition the following internal standard is applied:

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:

Sakura Finetek Europe B.V.
Tissue-Tek®
SAKURA
Flemingweg 10a - 2408 AV Alphen a/d Rijn
The Netherlands

Alphen aan den Rijn,

September 5, 2014