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:	Tissue Embedding Console System
Model name/number:	Tissue-Tek® TEC™ 6 / 5114 consists of: Tissue-Tek® TEC™ 6 Embedding Module / 5112 Tissue-Tek® TEC™ 6 Cryo Module / 5113

Manufactured by:

Sakura Seiki Co. Ltd., 75-5 Imojiya, Chikuma-shi, Nagano-ken, Japan

in accordance with the following Directives:

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/EU	Conforms with the substance restrictions of the Restriction of Hazardous Substances Directive and its amending directives.

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

EN ISO13485:2012, EN ISO14971:2012, EN 61010-1:2010, EN 61326-1:2013 and EN 50581:2012.

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 Directives.

Signed:

C.Koeman
General Manager

Digitally signed by Bolocan Vladimir
Date: 2019.11.14 14:29:48 EET
Reason: MoldSign Signature
Location: Moldova

Alphen aan den Rijn, 17 October 2018