DECLARATION OF CONFORMITY

Manufacturer: 3DHISTECH Ltd.
29-33. Konkoly-Thege M. street
Budapest
Hungary
H-1121

Product: Tissue microarrays creator with external PSU
Modell/Type ref.: TMA Master 01

Year of manufacture: 2012

Intended use: CE marked laboratory equipment

This declaration relates to conformity with the following standards:

IEC 61326:1997
IEC 61326/A1:1998
IEC 61326/A2:2000
IEC 61326:2002 (only Annexes E and F)
IEC 61010-1:2001 (ed. 2)
National Differences of US, CA

I, the undersigned Dr. Bela Molnar, the CEO of the 3DHISTEC Ltd, hereby declare under own sole responsibility that

- the model listed above to which this declaration relates is in conformity with the technical requirements of the standards listed above;

- the management system of 3DHISTECH Ltd. has been assessed and certified as meeting the requirements of ISO 9001:2008 and ISO 13485:2004 for the following activities: development, assembling, testing and sales of digital histological lab systems;
the following standards are applied by the 3DHISTECH Ltd:


I, the undersigned Dr. Bela Molnar, the CEO of the 3DHISTECH Ltd. declare that the product shall be installed, maintained and used for its intended application in accordance with Professional Practices, relevant installation Standard(s) and 3DHISTECH Ltd’s instructions.

Budapest, 16th October, 2012

Manufacturer Representative: Dr. Béla Molnár, CEO

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