EC DECLARATION OF CONFORMITY
(IVD reagents)

CE MARKING

Declaration of conformity according to Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in-vitro diagnostic medical devices.

We, **Klinipath B.V.**, Typograaf 16, 6921 VB, DUIVEN, The Netherlands;

Manufacturer of **Synergy Standard kit for Tissue Processing,** classified as per GIVD code no. 13 07 01 04, EDMA Term *Embedding Media*, with related product numbers:

- SYNS310-01H/S/T Synergy Standard kit hopper/separate/stacked version color white
- SYNS310-02H/S/T Synergy Standard kit hopper/separate/stacked version color yellow
- SYNS310-03H/S/T Synergy Standard kit hopper/separate/stacked version color blue
- SYNS310-04H/S/T Synergy Standard kit hopper/separate/stacked version color pink
- SYNS310-05H/S/T Synergy Standard kit hopper/separate/stacked version color green

Produced in EU, by Klinipath B.V.;

Declare under its sole responsibility to comply all obligations as per **Article 9 "Conformity assessment procedures" indent 1, procedure referred to Annex III, art. 1 to 5 of DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of 27 October 1998, on in vitro diagnostic medical devices** and to apply CE MARKING.

To guarantee consistent application of D98/79/EC, **Klinipath B.V.** developed and maintains management systems and technical files as per harmonized standards under the directive (Official Journal of European Union; publication 2013/C 22/03), such as:

- **EN ISO 13485: 2012**, Medical Devices - Quality Management Systems - Requirements for regulatory purposes (OJ 30.8.2012).
- **EN ISO 14971: 2012**, Medical Devices - Application of risk management to medical devices (OJ 30.8.2012).
- **EN ISO 18113-1: 2011**, In vitro diagnostics medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements (OJ 27.4.2012).
- **EN ISO 18113-2: 2011**, In vitro diagnostics medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic reagents for professional use (OJ 27.4.2012).

Klinipath B.V.
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Duiven, as of May 20, 2014

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Leon Faber, CEO