

## EU DECLARATION OF CONFORMITY – System II Hex

**Date:** 09/08/2021

This Declaration of Conformity has been issued solely by CellPath Limited (Company Number 01831261) in accordance with the definitions and regulations as described in the **EU Regulation 2017/746 of The European Parliament and of the Council on In-Vitro Diagnostic Medical Devices**.

### General Information

|   |   |
|---|---|
| Manufacturer  | CellPath Limited  |
| Address of Production Facility                                | CellPath Ltd<br>Unit 80, Mochdre Enterprise Park<br>Newtown<br>Powys<br>Mid Wales, UK<br>SY16 4LE   |
| Authorized Representative                                     | Emergo Europe (NL-AR-000000116)<br>Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands   |
| Product Name  | Histological tissue cassette IVD  |
| Product Description   | A small device intended to be used in the laboratory to support/contain clinical tissue specimens (e.g., biopsy samples) to facilitate specimen processing [e.g., fixation (encapsulation in paraffin wax), dehydration, infiltration] in preparation for subsequent cytological or histological examination, and storage. It is in the form of a synthetic polymer container, with or without a lid, with drainage holes to maximize fluid exposure during tissue submersion in a parent device into which the container is loaded. This is a single-use device. |
| Product Classification  | CLASS A   |
| <i>(Classified in accordance with EU Regulation 2017/746)</i> |   |

### Registered Office:

CellPath Ltd, 80 Mochdre Enterprise Park,  
Newtown, Powys, SY16 4LE Mid Wales, UK  
Registration Number: 01831261

Template reference number: 01.503.863 V1

**HTA**  
Licence No. 12434



| DEVICE(S) INFORMATION |                |                  |  |                    |
|-----------------------|----------------|------------------|--|--------------------|
| PART NUMBER           | GTIN           | UDI-DI           | DESCRIPTION                                      | YEAR OF CE MARKING |
| EAD-0102-00A          | 05056256104899 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - WHITE                 | 2005               |
| EAD-0102-03A          | 05056256113709 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - WHITE (LOOSE)         | 2016               |
| EAD-0102-04H          | 05056256113716 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - WHITE (HOPPERED)      | 2016               |
| EAD-0102-72B          | 05056256113723 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - WHITE (THREADED)      | 2016               |
| EAD-0104-03A          | 05056256113730 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - GREEN (LOOSE)         | 2016               |
| EAD-0104-04H          | 05056256113747 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - GREEN (HOPPERED)      | 2016               |
| EAD-0104-72B          | 05056256113754 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - GREEN (THREADED)      | 2016               |
| EAD-0105-03A          | 05056256113761 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - GREY (LOOSE)          | 2016               |
| EAD-0105-04H          | 05056256113778 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - GREY (HOPPERED)       | 2016               |
| EAD-0105-72B          | 05056256113785 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - GREY (THREADED)       | 2016               |
| EAD-0106-03A          | 05056256113792 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - BLUE (LOOSE)          | 2016               |
| EAD-0106-04H          | 05056256113808 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - BLUE (HOPPERED)       | 2016               |
| EAD-0106-72B          | 05056256113815 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - BLUE (THREADED)       | 2016               |
| EAD-0107-03A          | 05056256114447 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - ORANGE (LOOSE)        | 2005               |
| EAD-0107-04H          | 05056256114454 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - ORANGE (HOPPERED)     | 2005               |
| EAD-0107-72B          | 05056256114461 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - ORANGE (THREADED)     | 2015               |
| EAD-0108-03A          | 05056256114478 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - PINK (LOOSE)          | 2005               |
| EAD-0108-04H          | 05056256114485 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - PINK (HOPPERED)       | 2005               |
| EAD-0108-72B          | 05056256114492 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - PINK (THREADED)       | 2015               |
| EAD-0109-03A          | 05056256114508 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - YELLOW (LOOSE)        | 2005               |
| EAD-0109-04H          | 05056256114515 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - YELLOW (HOPPERED)     | 2005               |
| EAD-0109-72B          | 05056256114522 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - YELLOW (THREADED)     | 2015               |
| EAD-0110-03A          | 05056256114539 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - RED (LOOSE)           | 2005               |
| EAD-0110-04H          | 05056256114546 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - RED (HOPPERED)        | 2005               |
| EAD-0110-72B          | 05056256114553 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - RED (THREADED)        | 2015               |
| EAD-0111-03A          | 05056256114560 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - PEACH (LOOSE)         | 2005               |
| EAD-0111-04H          | 05056256114577 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - PEACH (HOPPERED)      | 2005               |
| EAD-0111-72B          | 05056256114775 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - PEACH (THREADED)      | 2015               |
| EAD-0112-03A          | 05056256114584 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - TAN (LOOSE)           | 2005               |
| EAD-0112-04H          | 05056256114591 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - TAN (HOPPERED)        | 2005               |
| EAD-0112-72B          | 05056256114607 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - TAN (THREADED)        | 2015               |
| EAD-0115-03A          | 05056256114614 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - BROWN (LOOSE)         | 2005               |
| EAD-0115-04H          | 05056256114621 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - BROWN (HOPPERED)      | 2005               |
| EAD-0115-72B          | 05056256114638 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - BROWN (THREADED)      | 2015               |
| EAD-0116-03A          | 05056256114652 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - DARK BLUE (LOOSE)     | 2005               |
| EAD-0116-04H          | 05056256114669 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - DARK BLUE (HOPPERED)  | 2005               |
| EAD-0116-72B          | 05056256114676 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - DARK BLUE (THREADED)  | 2015               |
| EAD-0118-03A          | 05056256114683 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - DARK GREEN (LOOSE)    | 2005               |
| EAD-0118-04H          | 05056256114690 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - DARK GREEN (HOPPERED) | 2005               |
| EAD-0118-72B          | 05056256114706 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - DARK GREEN (THREADED) | 2015               |
| EAD-0119-03A          | 05056256114713 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - LAVENDER (LOOSE)      | 2005               |
| EAD-0119-04H          | 05056256114720 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - LAVENDER (HOPPERED)   | 2005               |
| EAD-0119-72B          | 05056256114737 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - LAVENDER (THREADED)   | 2015               |
| EAD-0120-03A          | 05056256114744 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - TURQUOISE (LOOSE)     | 2005               |
| EAD-0120-04H          | 05056256114751 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - TURQUOISE (HOPPERED)  | 2005               |
| EAD-0120-72B          | 05056256114768 | 05056256EAD001WP | SYSTEM II HEX - CASSETTE - TURQUOISE (THREADED)  | 2015               |

Conformity to the aforementioned regulation is demonstrated by the company's compliance to the following international manufacturing standard:

Template reference number: 01.503.863 V1

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- **EN ISO 13485:2016** - Medical Devices, Quality Management Systems - Requirements for Regulatory Purposes

|                                      |   |
|--------------------------------------|---|
| Signed on behalf of the Manufacturer | CellPath Limited  |
| Address of Issue                     | CellPath Ltd<br>Unit 80, Mochdre Enterprise Park Newtown<br>Powys<br>Mid Wales, UK SY16 4LE |
| Date of Issue                        | 09/08/2021  |
| Name of Signatory                    | Hannah Moore  |
| Position of Signatory                | Product Manager   |
| Signature                            | <u>H Moore</u><br><small>H Moore (Aug 9, 2021 13:22 GMT+1)</small>                          |