

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

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|---|---|
| Manufacturer | CellPath Limited |
| Address of Production Facility | CellPath Ltd Unit 80, Mochdre Enterprise Park Newtown Powys Mid Wales, UK SY16 4LE |
| Authorized Representative | Emergo Europe (NL-AR-000000116) Prinsessegracht 20 2514 AP The Hague 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

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|--------------------------------------|---|
| Signed on behalf of the Manufacturer | CellPath Limited |
| Address of Issue | CellPath Ltd Unit 80, Mochdre Enterprise Park Newtown Powys 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> <small>H Moore (Aug 9, 2021 13:22 GMT+1)</small> |