

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 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

Registered Office:

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

HTA
 Licence No. 12434



- **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 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>