

## EU DECLARATION OF CONFORMITY – SYSTEM III BIOPSY

Date: 22/07/2021

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 <i>(Classified in accordance with EU Regulation 2017/746)</i>	CLASS A

Part Number	GTIN	UDI-DI	Device(s) Information	
			Description	Year of CE Marking
EAI-0302-10A	05056256113341	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - WHITE (LOOSE INKJET)	2015
EAI-0302-72B	05056256113358	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - WHITE (THREADED INKJET)	2015
EAI-0304-10A	05056256113365	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREEN (LOOSE INKJET)	2015
EAI-0304-72B	05056256100211	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREEN (THREADED INKJET)	2015
EAI-0305-10A	05056256100228	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREY (LOOSE INKJET)	2015
EAI-0305-72B	05056256100235	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREY (THREADED INKJET)	2015
EAI-0306-10A	05056256100242	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BLUE (LOOSE INKJET)	2015
EAI-0306-72B	05056256100259	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BLUE (THREADED INKJET)	2015
EAI-0307-10A	05056256100266	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - ORANGE (LOOSE INKJET)	2015
EAI-0307-72B	05056256100273	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - ORANGE (THREADED INKJET)	2015
EAI-0308-10A	05056256113372	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PINK (LOOSE INKJET)	2015
EAI-0308-72B	05056256100297	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PINK (THREADED INKJET)	2015
EAI-0309-10A	05056256100303	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - YELLOW (LOOSE INKJET)	2015
EAI-0309-72B	05056256100310	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - YELLOW (THREADED INKJET)	2015
EAI-0310-10A	05056256100327	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - RED (LOOSE INKJET)	2015
EAI-0310-72B	05056256100334	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - RED (THREADED INKJET)	2015
EAI-0311-10A	05056256100341	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PEACH (LOOSE INKJET)	2015
EAI-0311-72B	05056256100358	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PEACH (THREADED INKJET)	2015
EAI-0312-10A	05056256100365	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TAN (LOOSE INKJET)	2015
EAI-0312-72B	05056256100372	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TAN (THREADED INKJET)	2015
EAI-0315-10A	05056256100389	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BROWN (LOOSE INKJET)	2015
EAI-0315-72B	05056256100396	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BROWN (THREADED INKJET)	2015
EAI-0316-10A	05056256100402	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK BLUE (LOOSE INKJET)	2015
EAI-0316-72B	05056256100419	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK BLUE (THREADED INKJET)	2015
EAI-0318-10A	05056256100426	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK GREEN (LOOSE INKJET)	2015
EAI-0318-72B	05056256100433	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK GREEN (THREADED INKJET)	2015
EAI-0319-10A	05056256100440	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - LAVENDER (LOOSE INKJET)	2015
EAI-0319-72B	05056256100457	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - LAVENDER (THREADED INKJET)	2015
EAI-0320-10A	05056256100464	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TURQUOISE (LOOSE INKJET)	2015
EAI-0320-72B	05056256100471	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TURQUOISE (THREADED INKJET)	2015
EAI-0602-10A	05056256103526	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - WHITE (LOOSE THERMAL)	2018
EAI-0602-72B	05056256102321	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - WHITE (THREADED THERMAL)	2018
EAI-0604-10A	05056256103533	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREEN (LOOSE THERMAL)	2018
EAI-0604-72B	05056256102314	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREEN (THREADED THERMAL)	2018
EAI-0605-10A	05056256103540	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREY (LOOSE THERMAL)	2018
EAI-0605-72B	05056256103557	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREY (THREADED THERMAL)	2018
EAI-0606-10A	05056256103564	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BLUE (LOOSE THERMAL)	2018
EAI-0606-72B	05056256103571	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BLUE (THREADED THERMAL)	2018
EAI-0607-10A	05056256103588	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - ORANGE (LOOSE THERMAL)	2018
EAI-0607-72B	05056256102345	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - ORANGE (THREADED THERMAL)	2018
EAI-0608-10A	05056256103618	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PINK (LOOSE THERMAL)	2018
EAI-0608-72B	05056256103601	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PINK (THREADED THERMAL)	2018
EAI-0609-10A	05056256103625	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - YELLOW (LOOSE THERMAL)	2018
EAI-0609-72B	05056256102338	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - YELLOW (THREADED THERMAL)	2018
EAI-0610-10A	05056256103687	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - RED (LOOSE THERMAL)	2018
EAI-0610-72B	05056256103694	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - RED (THREADED THERMAL)	2018
EAI-0611-10A	05056256103700	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PEACH (LOOSE THERMAL)	2018
EAI-0611-72B	05056256103717	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PEACH (THREADED THERMAL)	2018
EAI-0612-10A	05056256103724	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TAN (LOOSE THERMAL)	2018
EAI-0612-72B	05056256103731	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TAN (THREADED THERMAL)	2018
EAI-0615-10A	05056256103748	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BROWN (LOOSE THERMAL)	2018
EAI-0615-72B	05056256103755	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BROWN (THREADED THERMAL)	2018
EAI-0616-10A	05056256103762	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK BLUE (LOOSE THERMAL)	2018

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<b>EAI-0616-72B</b>	05056256103779	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK BLUE (THREADED THERMAL)	2018
<b>EAI-0618-10A</b>	05056256103786	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK GREEN (LOOSE THERMAL)	2018
<b>EAI-0618-72B</b>	05056256103793	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK GREEN (THREADED THERMAL)	2018
<b>EAI-0619-10A</b>	05056256103809	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - LAVENDER (LOOSE THERMAL)	2018
<b>EAI-0619-72B</b>	05056256103816	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE THERMAL- LAVENDER (THREADED THERMAL)	2018
<b>EAI-0620-10A</b>	05056256103823	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TURQUOISE (LOOSE THERMAL)	2018
<b>EAI-0620-72B</b>	05056256103830	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE THERMAL- TURQUOISE (THREADED THERMAL)	2018

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

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

Signed on behalf of the Manufacturer                      CellPath Limited

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Date of Issue                                      22/07/2021

Name of Signatory                              Paul Webber

Position of Signatory                              Joint Managing Director

Signature    *Paul Webber*  
Paul Webber (Jul 22, 2021 15:34 GMT+1)

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