

**EU DECLARATION OF CONFORMITY – SYSTEM III BIOPSY CASSETTES**

**Date:** 12/07/2023

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 (GB-MF-000022744) Unit 80, Mochdre Enterprise Park Newtown, Powys Mid Wales, UK SY16 4LE
EU Authorised Representative	EMERGO EUROPE (NL-AR-000000116) Westervoortsedijk 60, 6827 AT Arnhem 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 Rule 5 IVDR)</i>	CLASS A

**Registered Office:**

CellPath Ltd, 3rd Floor 1 Ashley Road,  
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Reg. No. 01831261

**DEVICE(S) INFORMATION**

PART NUMBER	GTIN	BASIC UDI-DI	DESCRIPTION	YEAR OF CE MARKING
EAI-0602-10A	05056256103526	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - WHITE (LOOSE)	2018
EAI-0602-72B	05056256102321	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - WHITE (THREADED)	2018
EAI-0604-10A	05056256103533	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREEN (LOOSE)	2018
EAI-0604-72B	05056256102314	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREEN (THREADED)	2018
EAI-0605-10A	05056256103540	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREY (LOOSE)	2018
EAI-0605-72B	05056256103557	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - GREY (THREADED)	2018
EAI-0606-10A	05056256103564	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BLUE (LOOSE)	2018
EAI-0606-72B	05056256103571	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BLUE (THREADED)	2018
EAI-0607-10A	05056256103588	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - ORANGE (LOOSE)	2018
EAI-0607-72B	05056256102345	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - ORANGE (THREADED)	2018
EAI-0608-10A	05056256103618	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PINK (LOOSE)	2018
EAI-0608-72B	05056256103601	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PINK (THREADED)	2018
EAI-0609-10A	05056256103625	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - YELLOW (LOOSE)	2018
EAI-0609-72B	05056256102338	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - YELLOW (THREADED)	2018
EAI-0610-10A	05056256103687	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - RED (LOOSE)	2018
EAI-0610-72B	05056256103694	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - RED (THREADED)	2018
EAI-0611-10A	05056256103700	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PEACH (LOOSE)	2018
EAI-0611-72B	05056256103717	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - PEACH (THREADED)	2018
EAI-0612-10A	05056256103724	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TAN (LOOSE)	2018
EAI-0612-72B	05056256103731	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TAN (THREADED)	2018
EAI-0615-10A	05056256103748	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BROWN (LOOSE)	2018
EAI-0615-72B	05056256103755	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - BROWN (THREADED)	2018
EAI-0616-10A	05056256103762	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK BLUE (LOOSE)	2018
EAI-0616-72B	05056256103779	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK BLUE (THREADED)	2018
EAI-0618-10A	05056256103786	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK GREEN (LOOSE)	2018
EAI-0618-72B	05056256103793	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - DARK GREEN (THREADED)	2018
EAI-0619-10A	05056256103809	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - LAVENDER (LOOSE)	2018
EAI-0619-72B	05056256103816	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - LAVENDER (THREADED)	2018
EAI-0620-10A	05056256103823	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TURQUOISE (LOOSE)	2018
EAI-0620-72B	05056256103830	05056256EAI001XS	SYSTEM III BIOPSY CASSETTE - TURQUOISE (THREADED)	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

Address of Issue CellPath Ltd  
Unit 80, Mochdre Enterprise Park  
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Date of Issue 12/07/2023

Name of Signatory Alice Parry

Position of Signatory Regulatory Project Manager

Signature *Alice Parry*  
Alice Parry (Jul 13, 2023 11:51 GMT+1)

# EU - Declaration of Conformity - System III Biopsy Cassette

Final Audit Report

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