

EU DECLARATION OF CONFORMITY – SYSTEM III MICRO BIOPSY CASSETTES

Date: 01/11/2021

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
EU Authorised 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

DEVICE(S) INFORMATION

PART NUMBER	GTIN	UDI-DI	DESCRIPTION	YEAR OF CE MARKING
EAI-0402-10A	05056256113327	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - WHITE (LOOSE INKJET)	2015
EAI-0402-72B	05056256113334	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - WHITE (THREADED INKJET)	2015
EAI-0404-10A	05056256100785	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - GREEN (LOOSE INKJET)	2015
EAI-0404-72B	05056256100792	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - GREEN (THREADED INKJET)	2015
EAI-0405-10A	05056256100808	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - GREY (LOOSE INKJET)	2015
EAI-0405-72B	05056256100815	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - GREY (THREADED INKJET)	2015
EAI-0406-10A	05056256100822	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - BLUE (LOOSE INKJET)	2015
EAI-0406-72B	05056256100839	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - BLUE (THREADED INKJET)	2015
EAI-0407-10A	05056256100846	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - ORANGE (LOOSE INKJET)	2015
EAI-0407-72B	05056256100853	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - ORANGE (THREADED INKJET)	2015
EAI-0408-10A	05056256100860	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - PINK (LOOSE INKJET)	2015
EAI-0408-72B	05056256100877	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - PINK (THREADED INKJET)	2015
EAI-0409-10A	05056256100884	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - YELLOW (LOOSE INKJET)	2015
EAI-0409-72B	05056256100891	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - YELLOW (THREADED INKJET)	2015
EAI-0410-10A	05056256100907	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - RED (LOOSE INKJET)	2015
EAI-0410-72B	05056256100914	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - RED (THREADED INKJET)	2015
EAI-0411-10A	05056256100938	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - PEACH (LOOSE INKJET)	2015
EAI-0411-72B	05056256100945	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - PEACH (THREADED INKJET)	2015
EAI-0412-10A	05056256100952	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - TAN (LOOSE INKJET)	2015
EAI-0412-72B	05056256100969	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - TAN (THREADED INKJET)	2015
EAI-0415-10A	05056256100976	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - BROWN (LOOSE INKJET)	2015
EAI-0415-72B	05056256100983	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - BROWN (THREADED INKJET)	2015
EAI-0416-10A	05056256100990	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - DARK BLUE (LOOSE INKJET)	2015
EAI-0416-72B	05056256101003	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - DK BLUE (THREADED INKJET)	2015
EAI-0418-10A	05056256101010	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - DARK GREEN (LOOSE INKJET)	2015
EAI-0418-72B	05056256101027	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE -DK GREEN (THREADED INKJET)	2015
EAI-0419-10A	05056256101034	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - LAVENDER (LOOSE INKJET)	2015
EAI-0702-10A	05056256102413	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - WHITE (LOOSE THERMAL)	2018
EAI-0702-72B	05056256103847	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - WHITE (THREADED THERMAL)	2018

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EAI-0704-10A	05056256102420	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - GREEN (LOOSE THERMAL)	2018
EAI-0704-72B	05056256102307	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - GREEN (THREADED THERMAL)	2018
EAI-0705-10A	05056256103854	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - GREY (LOOSE THERMAL)	2018
EAI-0705-72B	05056256103861	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - GREY (THREADED THERMAL)	2018
EAI-0706-10A	05056256103878	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - BLUE (LOOSE THERMAL)	2018
EAI-0706-72B	05056256103885	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - BLUE (THREADED THERMAL)	2018
EAI-0707-10A	05056256103892	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - ORANGE (LOOSE THERMAL)	2018
EAI-0707-72B	05056256103908	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - ORANGE (THREADED THERMAL)	2018
EAI-0708-10A	05056256103915	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - PINK (LOOSE THERMAL)	2018
EAI-0708-72B	05056256103502	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - PINK (THREADED THERMAL)	2018
EAI-0709-10A	05056256102369	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - YELLOW (LOOSE THERMAL)	2018
EAI-0709-72B	05056256103922	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - YELLOW (THREADED THERMAL)	2018
EAI-0710-10A	05056256103939	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - RED (LOOSE THERMAL)	2018
EAI-0710-72B	05056256103946	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - RED (THREADED THERMAL)	2018
EAI-0711-10A	05056256103953	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - PEACH (LOOSE THERMAL)	2018
EAI-0711-72B	05056256103960	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - PEACH (THREADED THERMAL)	2018
EAI-0712-10A	05056256103977	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - TAN (LOOSE THERMAL)	2018
EAI-0712-72B	05056256103984	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - TAN (THREADED THERMAL)	2018
EAI-0715-10A	05056256104011	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - BROWN (LOOSE THERMAL)	2018
EAI-0715-72B	05056256104028	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - BROWN (THREADED THERMAL)	2018
EAI-0716-10A	05056256104035	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - DARK BLUE (LOOSE THERMAL)	2018
EAI-0716-72B	05056256104042	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - DK BLUE (THREADED THERMAL)	2018
EAI-0718-10A	05056256104059	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - DARK GREEN (LOOSE THERMAL)	2018
EAI-0718-72B	05056256104066	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE-DK GREEN (THREADED THERMAL)	2018
EAI-0719-10A	05056256103083	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - LAVENDER (LOOSE THERMAL)	2018
EAI-0719-72B	05056256104073	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE-LAVENDER (THREADED THERMAL)	2018
EAI-0720-10A	05056256104080	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE - TURQUOISE (LOOSE THERMAL)	2018
EAI-0720-72B	05056256104097	05056256EAI001XS	SYSTEM III MICRO BIOPSY CASSETTE-TURQUOISE (THREADED THERMAL)	2018

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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 01/11/2021

Name of Signatory Hannah Moore

Position of Signatory Product Manager

Signature H Moore

H Moore (Nov 3, 2021 09:50 GMT)

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