

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

Address of Issue CellPath Ltd
Unit 80, Mochdre Enterprise Park
Newtown, Powys
Mid Wales, UK
SY16 4LE

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)