

EU DECLARATION OF CONFORMITY – System II Hex Laser - Cassettes

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 <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
EAD-0202-072B	05056256105926	05056256EAD001WP	SYSTEM II HEX - CASSETTE - WHITE LASER (THREADED)	2019
EAD-0204-072B	05056256105933	05056256EAD001WP	SYSTEM II HEX - CASSETTE - GREEN LASER (THREADED)	2019
EAD-0205-72B	05056256105940	05056256EAD001WP	SYSTEM II HEX - CASSETTE - GREY LASER (THREADED)	2019
EAD-0206-72B	05056256105957	05056256EAD001WP	SYSTEM II HEX - CASSETTE - BLUE LASER (THREADED)	2019
EAD-0207-72B	05056256105964	05056256EAD001WP	SYSTEM II HEX - CASSETTE - ORANGE LASER (THREADED)	2019
EAD-0208-72B	05056256105971	05056256EAD001WP	SYSTEM II HEX - CASSETTE - PINK LASER (THREADED)	2019
EAD-0209-72B	05056256105988	05056256EAD001WP	SYSTEM II HEX - CASSETTE - YELLOW LASER (THREADED)	2019
EAD-0211-72B	05056256106008	05056256EAD001WP	SYSTEM II HEX - CASSETTE - PEACH LASER (THREADED)	2019
EAD-0212-72B	05056256106015	05056256EAD001WP	SYSTEM II HEX - CASSETTE - TAN LASER (THREADED)	2019
EAD-0219-72B	05056256106053	05056256EAD001WP	SYSTEM II HEX - CASSETTE - LAVENDER LASER (THREADED)	2019

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

09/08/2021

Name of Signatory

Hannah Moore

Position of Signatory

Product Manager

Signature


 H Moore (Aug 9, 2021 13:04 GMT+1)

Registered Office:

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Registration Number: 01831261