

EU DECLARATION OF CONFORMITY – System II Hex Cassette Lid (Loose)

Date: 31/08/2021

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

Registered Office:

CellPath Ltd, 80 Mochdre Enterprise Park,
Newtown, Powys, SY16 4LE Mid Wales, UK
Registration Number: 01831261

DEVICE(S) INFORMATION				
PART NUMBER	GTIN	UDI-DI	DESCRIPTION	YEAR OF CE MARKING
EAE-0102-03A	05056256115109	05056256EAD001WP	SYSTEM II HEX-CASSETTE LID - WHITE (LOOSE)	2003
EAE-0110-03A	05056256102628	05056256EAD001WP	SYSTEM II HEX-CASSETTE LID - RED (LOOSE)	2005

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 31/08/2021

Name of Signatory Hannah Moore

Position of Signatory Product Manager

Signature 
H Moore (Aug 31, 2021 10:07 GMT+1)

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