

EU DECLARATION OF CONFORMITY – OCT

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** and **Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH)**.

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	Tissue freezing/embedding medium IVD
Product Description	A tissue freezing and embedding material intended to be used as an embedding matrix for the preparation and processing of frozen sections from biological tissues or clinical specimens.
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
KMA-0100-00A	05056256114645	05056256KMA0014P	OCT EMBEDDING MATRIX - 125ml	2006

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

H Moore (Aug 9, 2021 11:37 GMT+1)