

## EU DECLARATION OF CONFORMITY – XMARK TISSUE MARKING DYES

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	Biopsy tissue marking dye kit IVD
Product Description	A coloured solution intended to be used to permanently mark the surgical margins and/or other general areas of interest on a tissue biopsy specimen; it is not intended to stain a tissue section for the visualization of intra/extracellular elements. It is one of a set, or a set of multiple colours (e.g., red, blue, black, green, violet and/or orange) which can withstand tissue processing (e.g., tissue fixation, freezing) without fading or bleeding. Applicators for precise marking or spreading of the dye onto the tissue specimen may be included.
Product Classification (Classified in accordance with EU Regulation 2017/746)	CLASS A

### Registered Office:

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


PART NUMBER	GTIN	UDI-DI	DEVICE(S) INFORMATION	
			DESCRIPTION	YEAR OF CE MARKING
RCA-0101-00A	05056256114041	05056256RCA00144	XMARK - TISSUE MARKING DYE - BLACK - 60ML BOTTLE	2018
RCA-0101-00B	05056256109672	05056256RCA00144	XMARK - TISSUE MARKING DYE - BLACK - 60ML BOTTLE	2020
RCA-0101-00C	05056256114058	05056256RCA00144	XMARK - TISSUE MARKING DYE - BLACK - 250ML BOTTLE	2018
RCA-0101-00D	05056256109689	05056256RCA00144	XMARK - TISSUE MARKING DYE - BLACK - 250ML BOTTLE	2020
RCA-0104-00A	05056256114065	05056256RCA00144	XMARK - TISSUE MARKING DYE - GREEN - 60ML BOTTLE	2018
RCA-0104-00B	05056256109696	05056256RCA00144	XMARK - TISSUE MARKING DYE - GREEN - 60ML BOTTLE	2020
RCA-0104-00C	05056256114072	05056256RCA00144	XMARK - TISSUE MARKING DYE - GREEN - 250ML BOTTLE	2018
RCA-0104-00D	05056256109702	05056256RCA00144	XMARK - TISSUE MARKING DYE - GREEN - 250ML BOTTLE	2020
RCA-0106-00A	05056256114089	05056256RCA00144	XMARK - TISSUE MARKING DYE - BLUE - 60ML BOTTLE	2018
RCA-0106-00B	05056256109719	05056256RCA00144	XMARK - TISSUE MARKING DYE - BLUE - 60ML BOTTLE	2020
RCA-0106-00C	05056256114096	05056256RCA00144	XMARK - TISSUE MARKING DYE - BLUE - 250ML BOTTLE	2018
RCA-0106-00D	05056256109726	05056256RCA00144	XMARK - TISSUE MARKING DYE - BLUE - 250ML BOTTLE	2020
RCA-0107-00A	05056256114102	05056256RCA00144	XMARK - TISSUE MARKING DYE - ORANGE - 60ML BOTTLE	2018
RCA-0107-00B	05056256109733	05056256RCA00144	XMARK - TISSUE MARKING DYE - ORANGE - 60ML BOTTLE	2020
RCA-0107-00C	05056256114119	05056256RCA00144	XMARK - TISSUE MARKING DYE - ORANGE - 250ML BOTTLE	2018
RCA-0107-00D	05056256109740	05056256RCA00144	XMARK - TISSUE MARKING DYE - ORANGE - 250ML BOTTLE	2020
RCA-0109-00A	05056256114126	05056256RCA00144	XMARK - TISSUE MARKING DYE - YELLOW - 60ML BOTTLE	2018
RCA-0109-00B	05056256109757	05056256RCA00144	XMARK - TISSUE MARKING DYE - YELLOW - 60ML BOTTLE	2020
RCA-0109-00C	05056256114133	05056256RCA00144	XMARK - TISSUE MARKING DYE - YELLOW - 250ML BOTTLE	2018
RCA-0109-00D	05056256109764	05056256RCA00144	XMARK - TISSUE MARKING DYE - YELLOW - 250ML BOTTLE	2020
RCA-0110-00A	05056256114140	05056256RCA00144	XMARK - TISSUE MARKING DYE - RED - 60ML BOTTLE	2018
RCA-0110-00B	05056256109771	05056256RCA00144	XMARK - TISSUE MARKING DYE - RED - 60ML BOTTLE	2020
RCA-0110-00C	05056256114157	05056256RCA00144	XMARK - TISSUE MARKING DYE - RED - 250ML BOTTLE	2018
RCA-0110-00D	05056256109788	05056256RCA00144	XMARK - TISSUE MARKING DYE - RED - 250ML BOTTLE	2020
RCA-0124-00A	05056256114164	05056256RCA00144	XMARK - TISSUE MARKING DYE - VIOLET - 60ML BOTTLE	2018
RCA-0124-00C	05056256114171	05056256RCA00144	XMARK - TISSUE MARKING DYE - VIOLET - 250ML BOTTLE	2018
RCA-0126-00A	05056256114188	05056256RCA00144	XMARK - TISSUE MARKING DYE - TEAL - 60ML BOTTLE	2018
RCA-0126-00C	05056256114195	05056256RCA00144	XMARK - TISSUE MARKING DYE - TEAL - 250ML BOTTLE	2018
RCA-0127-00A	05056256114201	05056256RCA00144	XMARK - TISSUE MARKING DYE - MAGENTA - 60ML BOTTLE	2018
RCA-0127-00C	05056256114218	05056256RCA00144	XMARK - TISSUE MARKING DYE - MAGENTA - 250ML BOTTLE	2018
RCB-0100-00A	05056256114225	05056256RCA00144	XMARK FIX - 250ML	2018
RCB-0300-00A	05056256103465	05056256RCA00144	XMARK INK SHIELD - 250ML	2018
RCB-0300-00B	05056256104738	05056256RCA00144	XMARK INK SHIELD - 250ML	2018

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  
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Date of Issue 09/08/2021  
Name of Signatory Hannah Moore  
Position of Signatory Product Manager  
Signature   
H Moore (Aug 9, 2021 15:04 GMT+1)