

**EU DECLARATION OF CONFORMITY – TRUSLICE**

**Date:** 22/04/2022

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	Histology/pathology manual tissue cutting set IVD
Product Description	A collection of non-powered benchtop devices designed to be used in a histopathology laboratory to stabilize a tissue specimen and facilitate manual cutting of tissue sections at selected thicknesses with a knife. It typically includes a flat cutting base/board, a hand-held tissue immobilization plate, graduated plates/inserts for selected-thickness tissue slices, and a knife. This is a reusable device.
Product Classification <i>(Classified in accordance with Rule 5 IVDR)</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
CBA-0100-00A	05056256114263	05056256CBA001VK	TRUSLICE – SPECIMEN CUT UP SYSTEM	2015
CBA-0100-00B	05056256114270	05056256CBA001VK	TRUSLICE – SURECUT BOARD – WHITE	2015
CBA-0100-05D	05056256114287	05056256CBA001VK	TRUSLICE – SMALL CUTTING INSERTS	2015
CBA-0100-05E	05056256114294	05056256CBA001VK	TRUSLICE – LARGE CUTTING INSERTS	2015
CBA-0100-25G	05056256114300	05056256CBA001VK	TRUSLICE – 2MM INSERTS (RED)	2015
CBA-0100-25H	05056256114317	05056256CBA001VK	TRUSLICE – 3MM INSERTS (YELLOW)	2015
CBA-0100-25I	05056256114324	05056256CBA001VK	TRUSLICE – 4MM INSERTS (GREEN)	2015
CBA-0100-25J	05056256114331	05056256CBA001VK	TRUSLICE – 5MM INSERTS (BLUE)	2015
CBA-0100-25K	05056256114348	05056256CBA001VK	TRUSLICE – MIXED INSERTS (EACH – RED, YELLOW, GREEN & BLUE)	2015
CBA-0100-99A	05056256114355	05056256CBA001VK	TRUSLICE – SPECIMEN CUT UP SYSTEM – STARTER KIT (EF)	2015
CBA-0106-00B	05056256114948	05056256CBA001VK	TRUSLICE – SURECUT BOARD – BLUE	2015
CBA-0200-00A	05056256114362	05056256CBA001VK	TRUSLICE DIGITAL – SPECIMEN CUT UP SYSTEM	2015
CBA-0200-00B	05056256114379	05056256CBA001VK	TRUSLICE – 75MM IMMOBILISATION PLATE	2015
CBA-0300-00A	05056256114386	05056256CBA001VK	TRUSLICE – 50MM IMMOBILISATION PLATE	2015
CBA-0300-00C	05056256114393	05056256CBA001VK	TRUSLICE – CALIBRATION SET	2015

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  
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Date of Issue 22/04/2022

Name of Signatory Hannah Moore

Position of Signatory Product Manager

Signature   
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