CellPath Ltd
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EU DECLARATION OF CONFORMITY – MICROTOME BLADES

Date: 04/08/2021

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	Microtome blade IVD, single use
Product Description	A flat, wedge-shaped, sharp blade intended to be mounted into a microtome to cut micro-thin slices of tissue that has been fixed, and usually impregnated, with paraffin wax. The resulting sections are mounted onto slides for staining and then viewing with a microscope. This is a single use device.
Product Classification *(Classified in accordance with EU Regulation 2017/746)*	CLASS A

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DEVICE(S) INFORMATION				
PART NUMBER	**GTIN**	**UDI-DI**	**DESCRIPTION**	**YEAR OF CE MARKING**
JDD-0300-00S	05056256113648	05056256JDD001ZR	CELLEDGE A+ - THIN SECTION MICROTOME BLADE - 5 SAMPLE BLADES	2012
JDD-0300-00A	05056256113655	05056256JDD001ZR	CELLEDGE A+ - THIN SECTION MICROTOME BLADE - 50 BLADES	2012
JDD-0500-00A	05056256102604	05056256JDD001ZR	CELLEDGE B+ - ROUTINE MICROTOME BLADE - 50 BLADES	2019
JDD-0600-00A	05056256105469	05056256JDD001ZR	CELLEDGE P+ - ROUTINE MICROTOME BLADE - 50 BLADES	2019
JDD-0200-00S	05056256113662	05056256JDD001ZR	CELLEDGE R+ - DURABLE MICROTOME BLADE - 5 SAMPLE BLADES	2012
JDD-0200-00A	05056256113679	05056256JDD001ZR	CELLEDGE R+ - DURABLE MICROTOME BLADE - 50 BLADES	2012
JDD-0100-00S	05056256113686	05056256JDD001ZR	CELLEDGE S+ - ROUTINE MICROTOME BLADE - 5 SAMPLE BLADES	2012
JDD-0100-00A	05056256113693	05056256JDD001ZR	CELLEDGE S+ - ROUTINE MICROTOME BLADE - 50 BLADES	2012

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	04/08/2021
Name of Signatory	Hannah Moore
Position of Signatory	Product Manager
Signature	H Moore H Moore (Aug 9, 2021 08:39 GMT+1)

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