

EU DECLARATION OF CONFORMITY – Microscope Slides

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	General specimen microscopy slide IVD, single-use.
Product Description	A glass or plastic microscopy slide intended to be used for the collection, and preservation and/or transport, of any type of clinical specimen or smear for analysis and/or other investigation. This is a single-use device.
Product Classification <i>(Classified in accordance with EU Regulation 2017/746)</i>	CLASS A

DEVICE(S) INFORMATION				
PART NUMBER	GTIN	UDI-DI	DESCRIPTION	YEAR OF CE MARKING
MAC-1400-02A	05056256113525	05056256MAZ0016U	CLARITEX SUPA MEGA SLIDE, PLAIN, 1.0-1.2mm, 90°, GROUND	2006
MAD-1400-02A	05056256113532	05056256MAZ0016U	CLARITEX SUPA MEGA SLIDE, TWINFROST, 1.0-1.2mm, 90°, GROUND	2006
MAE-1000-03P	05056256106930	05056256MAZ0016U	CLARITEX SLIDE, TWINFROST, 1.0-1.2mm, 90°, GROUND	2006
MAF-0102-03A	05056256113556	05056256MAZ0016U	CLARITEX SLIDE, WHITECOAT, 1.0-1.2mm, 90°, GROUND	2006
MAF-0102-03C	05056256113549	05056256MAZ0016U	CLARITEX SLIDE, WHITECOAT, 1.0-1.2mm, CLIPPED, GROUND	2007
MAF-0104-03A	05056256113563	05056256MAZ0016U	CLARITEX SLIDE, GREENCOAT, 1.0-1.2mm, 90°, GROUND	2006
MAF-0106-03A	05056256113570	05056256MAZ0016U	CLARITEX SLIDE, BLUECOAT, 1.0-1.2mm, 90°, GROUND	2006
MAF-0107-03A	05056256113587	05056256MAZ0016U	CLARITEX SLIDE, ORANGE COAT, 1.0-1.2mm, 90°, GROUND	2006
MAF-0108-03A	05056256113594	05056256MAZ0016U	CLARITEX SLIDE, PINK COAT, 1.0-1.2mm, 90°, GROUND	2006
MAF-0109-03A	05056256113600	05056256MAZ0016U	CLARITEX SLIDE, YELLOW COAT, 1.0-1.2mm, 90°, GROUND	2006
MAF-0110-03A	05056256113617	05056256MAZ0016U	CLARITEX SLIDE, PURPLE COAT, 1.0-1.2mm, 90°, GROUND	2006
MAG-1000-03P	05056256113624	05056256MAZ0016U	CLARITEX SLIDE, SINGLEFROST, 1.0-1.2mm, 90°, GROUND	2007
MAH-1000-03P	05056256113631	05056256MAZ0016U	CLARITEX SLIDE, PLAIN, 1.0-1.2mm, 90°, GROUND	2007
MDA-0102-55A	05056256106244	05056256MAZ0016U	CLARITEX PRO ADHESIVE SLIDE, WHITE COAT, 1.01.2mm, 90°, GND	2019
MDA-0104-55A	05056256106183	05056256MAZ0016U	CLARITEX PRO ADHESIVE SLIDE, GREEN COAT, 1.01.2mm, 90°, GND	2019
MDA-0106-55A	05056256106169	05056256MAZ0016U	CLARITEX PRO ADHESIVE SLIDE, BLUE COAT, 1.0-1.2mm, 90°, GND	2019
MDA-0107-55A	05056256106206	05056256MAZ0016U	CLARITEX PRO ADHESIVE SLIDE, ORANGE COAT, 1.0-1.2mm, 90°, GND	2019
MDA-0108-55A	05056256106220	05056256MAZ0016U	CLARITEX PRO ADHESIVE SLIDE, PINK COAT, 1.0-1.2mm, 90°, GND	2019
MDA-0109-55A	05056256106268	05056256MAZ0016U	CLARITEX PRO ADHESIVE SLIDE, YELLOW COAT, 1.0-1.2mm, 90°, GND	2019

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	 <small>H Moore (Dec 6, 2021 16:00 GMT)</small>

Registered Office:

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