

**EU DECLARATION OF CONFORMITY – COVERSLIPS**

**Date:** 21/04/2022

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	Microscope slide coverslip IVD
Product Description	A thin piece of glass or a plastic sheath placed over a specimen on a microscope slide, to serve as a physical barrier to protect the specimen from mechanical forces and environmental exposure. This is a single-use 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
SAF-5064-02A	05060470562991	05060470SAZ00149	CLARITEX SUPA MEGA COVERSLEIPS No 1.5 50 x 64mm	2005
SAG-5064-02A	05060470567361	05060470SAZ00149	CLARITEX SUPA MEGA COVERSLEIPS No 1.0 50 x 64mm	2005
SAH-2222-03A	05060470567378	05060470SAZ00149	CLARITEX COVERSLEIPS No 1.5 22 x 22mm	2003
SAH-2250-03A	05060470567408	05060470SAZ00149	CLARITEX COVERSLEIPS No 1.5 22 x 50mm	2003
SAH-2450-03A	05060470567453	05060470SAZ00149	CLARITEX COVERSLEIPS No 1.5 24 x 50mm	2003
SAJ-2222-03A	05060470567460	05060470SAZ00149	CLARITEX COVERSLEIPS No 1.0 22 x 22mm	2003
SAJ-2250-03A	05060470567491	05060470SAZ00149	CLARITEX COVERSLEIPS No 1.0 22 x 50mm	2003
SAJ-2450-03A	05060470567507	05060470SAZ00149	CLARITEX COVERSLEIPS No 1.0 24 x 50mm	2003

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 21/04/2022

Name of Signatory Hannah Moore

Position of Signatory Product Manager

Signature   
H Moore (Apr 22, 2022 13:51 GMT+1)