CellPath Ltd
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EU DECLARATION OF CONFORMITY – CELLSAFE+

Date: 21/07/2021

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
EU Authorised Representative	EMERGO EUROPE (NL-AR-000000116) Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name	Histological tissue cassette biopsy insert IVD
Product Description	A flexible and porous material designed to securely hold a biopsy specimen within a tissue cassette, to prevent loss of the specimen during specimen processing (e.g., fixation, dehydration, infiltration) in preparation for subsequent cytological or histological examination. The flexible and porous material (e.g., paper, synthetic polymer) is intended to allow infiltration of reagents and maximize fluid-exchange during tissue processing. It is available in various forms (e.g., sheet, bag, foam pad) and is placed in a tissue processing cassette, with the biopsy specimen wrapped or contained inside it. This is a single-use device.
Product Classification *(Classified in accordance with EU Regulation 2017/746)*	CLASS A

DEVICE(S) INFORMATION				
PART NUMBER	**GTIN**	**UDI-DI**	**DESCRIPTION**	**YEAR OF CE MARKING**
EBE-0201-02A	05060470564506	05060470EBE001S8	CELLSAFE+ BIOPSY CAPSULE - WHITE	2006
EBE-0201-03A	05060470564513	05060470EBE001S8	CELLSAFE+ BIOPSY CAPSULE - WHITE	2006
EBE-0301-02A	05060470564520	05060470EBE001S8	CELLSAFE+ BIOPSY CAPSULE - BLUE	2006
EBE-0301-03A	05060470564537	05060470EBE001S8	CELLSAFE+ BIOPSY CAPSULE - BLUE	2006

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 21/07/2021

Name of Signatory Paul Webber

Position of Signatory Joint Managing Director

Signature Paul Webber
Paul Webber (Jul 21, 2021 11:41 GMT+1)

CellSafe+ - Declaration of Conformity - EU

Final Audit Report 2021-03-16

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"CellSafe+ - Declaration of Conformity - EU" History

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