

EU DECLARATION OF CONFORMITY – CELLSAFE 5 BIOPSY CASSETTE

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 CellSafe 5 Biopsy Cassette

Product Description A small device intended to be used in the laboratory to support/contain clin biopsy samples) to facilitate specimen processing [e.g., fixation (encapsulat dehydration, infiltration] in preparation for subsequent cytological or histol storage. It is in the form of a synthetic polymer container, with or without a maximize fluid exposure during tissue submersion in a parent device into w This is a single-use device.

Product Classification Class A
(Classified in accordance with EU Regulation 2017/746

DEVICE(S) INFORMATION				
PART NUMBER	GTIN	UDI-DI	DESCRIPTION	YEAR OF CE MARKING
EBG-0201-02A	05060470564568	05060470EBG001SN	CELLSAFE 5 BIOPSY CASSETTE - WHITE	2008
EBG-0206-02A	05060470564575	05060470EBG001SN	CELLSAFE 5 BIOPSY CASSETTE - BLUE	2008

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
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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 12:03 GMT+1)

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Registration Number: 01831261

HTA
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