

EU DECLARATION OF CONFORMITY – DISPOCUT BOARD

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
Authorized Representative	Emergo Europe (NL-AR-000000116) Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name	Histology/pathology tissue cutting board IVD
Product Description	A stiff, plastic device designed to be used as a surface for cutting human tissues in a histopathology laboratory for subsequent in vitro diagnostic investigation. It is typically flat and rectangular in shape, with metric/imperial measurement graduations as a visual approximation aid. 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
CGB-0302-51A	05060470560805	05060470CGB001SG	DISPOCUT BOARD WHITE - A3 (297x420mm)	2003
CGB-0402-52A	05060470560812	05060470CGB001SG	DISPOCUT BOARD WHITE - A4 (297x210mm)	2003
CGB-0502-53A	05060470560829	05060470CGB001SG	DISPOCUT BOARD WHITE - A5 (148x210mm)	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 21/07/2021

Name of Signatory Paul Webber

Position of Signatory Joint Managing Director

Signature 
Paul Webber (Jul 21, 2021 16:40 GMT+1)

Registered Office:

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Registration Number: 01831261