CellPath Ltd
80 Mochdre Enterprise Park,
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EU DECLARATION OF CONFORMITY – *BITRAN BAGS*

Date: 29/07/2021

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	General tissue specimen container IVD, no additive
Product Description	A non-sterile covered plastic receptacle containing no additives intended to be used for the collection, and preservation and/or transport, of any type of tissue specimen (e.g., biopsy tissue) for analysis and/or other investigation. This is a single-use device.
Product Classification *(Classified in accordance with EU Regulation 2017/746)*	CLASS A

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DEVICE(S) INFORMATION				
PART NUMBER	**GTIN**	**UDI-DI**	**DESCRIPTION**	**YEAR OF CE MARKING**
WAA-0100-12A	05060470567736	05060470WAA001YB	BITRAN® BAG 2 INCH x 4 INCH (50x100mm)	2003
WAA-0200-12A	05060470567743	05060470WAA001YB	BITRAN® BAG 3 INCH x 6 INCH (80x150mm)	2003
WAA-0300-12A	05060470567750	05060470WAA001YB	BITRAN® BAG 6 INCH x 6 INCH (150x150mm)	2003
WAA-0400-12A	05060470567767	05060470WAA001YB	BITRAN® BAG 7 INCH x 8 INCH (180x200mm)	2003
WAA-0500-12A	05060470567774	05060470WAA001YB	BITRAN® BAG 9 INCH X 12 INCH (230x300mm)	2003
WAA-0600-12A	05060470567781	05060470WAA001YB	BITRAN® BAG 12 INCH x 12 INCH (300x300mm)	2003
WAA-0700-02A	05060470567798	05060470WAA001YB	BITRAN® BAG 16 INCH x 16 INCH (406x406mm)	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	29/07/2021
Name of Signatory	Hannah Moore
Position of Signatory	Product Manager
Signature	H Moore H Moore (Aug 9, 2021 08:37 GMT+1)