

**EU DECLARATION OF CONFORMITY – POTS & PAILS**

**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-00000116) Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name	General specimen container IVD, no additive, non-sterile
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 diagnostic specimen (e.g., urine, faeces, sputum, mucous, tissue) for analysis and/or other investigation. 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
BAC-0507-02A	05060470560041	05060470WAT0014K	CELLSTOR 120ml POT & LID – ORANGE (ASSEMBLED)	2006
BAE-0102-02A	05060470560065	05060470WAT0014K	CELLSTOR 20ml POT & LID - WHITE	2006
BAE-0207-02A	05060470560089	05060470WAT0014K	CELLSTOR 40ml POT & LID - ORANGE	2006
BAE-0307-02A	05060470560133	05060470WAT0014K	CELLSTOR 60ml POT & LID - ORANGE	2006
BAE-0309-02A	05060470560140	05060470WAT0014K	CELLSTOR 60ml POT & LID - YELLOW	2003
BAE-0407-02A	05060470560171	05060470WAT0014K	CELLSTOR 90ml POT & LID - ORANGE	2006
BAE-0507-02A	05060470560201	05060470WAT0014K	CELLSTOR 120ml POT & LID - ORANGE	2003
BAE-0602-02A	05060470563295	05060470WAT0014K	CELLSTOR 180ml POT & LID - WHITE	2007
WAT-2500-09A	05060470567934	05060470WAT0014K	TISSUESTOR 250 TUB - 250ml	2009
WAT-5000-09A	05060470567941	05060470WAT0014K	TISSUESTOR 500 TUB - 500ml	2009
WAT-8000-09A	05060470567958	05060470WAT0014K	TISSUESTOR 1000 TUB - 1 LITRE	2009
WAT-9100-09A	05060470567972	05060470WAT0014K	TISSUESTOR 2500 TUB - 2.5 LITRE	2009
WAT-9400-08A	05060470568009	05060470WAT0014K	TISSUESTOR 5000 TUB - 5 LITRE	2009
WAT-9600-01A	05060470568023	05060470WAT0014K	TISSUESTOR 10000 TUB - 10 LITRE	2009
WAT-9700-01A	05060470568047	05060470WAT0014K	TISSUESTOR 15000 TUB - 15 LITRE	2009
WAT-9800-01A	05060470568054	05060470WAT0014K	TISSUESTOR 20000 TUB - 20 LITRE	2009
WAT-9900-05A	05060470568061	05060470WAT0014K	TISSUESTOR 25000 TUB - 25 LITRE	2009

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 13:52 GMT+1)