

EU DECLARATION OF CONFORMITY – 10% FORMAL SALINE

Date: 10/05/2023

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 and **EU Regulation 1907/2006** of The European Parliament and of the Council on Registration, Evaluation, Authorization and Restriction of Chemicals (**REACH**).

General Information

Manufacturer	CellPath Limited
Address of Production Facility	CellPath Ltd (GB-MF-000022744) Unit 80, Mochdre Enterprise Park Newtown, Powys Mid Wales, UK SY16 4LE
EU Authorised Representative	EMERGO EUROPE (NL-AR-000000116) Westervoortsedijk 60, 6827 AT Arnhem The Netherlands
Product Name	General tissue specimen container IVD, formal saline
Product Description	A covered plastic receptacle containing 10% formal saline preservative solution (formalin) 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 Rule 5 IVDR)	CLASS A

DEVICE(S) INFORMATION

PART NUMBER	GTIN	BASIC UDI-DI	DESCRIPTION	YEAR OF CE MARKING
BAF-0110-01A	05060470567002	05060470BAF001QV	CELLSTOR - 1L - 10% FORMAL SALINE	2004
BAF-0110-25A	05060470560324	05060470BAF001QV	CELLSTOR - 5L - 10% FORMAL SALINE	2009
BAF-2100-70A	05060470560348	05060470BAF001QV	CELLSTOR POT - 120ml - 10% FORMAL SALINE	2003
BAF-5100-08A	05060470560362	05060470BAF001QV	CELLSTOR POT - 20ml - 10% FORMAL SALINE	2003
BAF-6100-08A	05060470560409	05060470BAF001QV	CELLSTOR POT - 60ml - 10% FORMAL SALINE	2003
BAF-9100-08A	05060470560423	05060470BAF001QV	CELLSTOR POT - 90ml - 10% FORMAL SALINE	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 10/05/2023

Name of Signatory Alice Parry

Position of Signatory Regulatory Project Manager

Signature *Alice Parry*