CellPath Ltd
80 Mochdre Enterprise Park,
Newtown, Powys,
SY16 4LE Mid Wales, UK

Tel: +44 (0) 1686 611 333
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Email: sales@cellpath.com
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**EU DECLARATION OF CONFORMITY –** *10% FORMAL SALINE*

**Date:** 05/08/2021

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** and **Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH).**

General Information

| | |
|---|---|
| Manufacturer | CellPath Limited |
| Address of Production Facility | CellPath Ltd<br>Unit 80, Mochdre Enterprise Park<br>Newtown<br>Powys<br>Mid Wales, UK<br>SY16 4LE |
| EU Authorised Representative | EMERGO EUROPE (NL-AR-000000116)<br>Prinsessegracht 20<br>2514 AP The Hague<br>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<br>*(Classified in accordance with EU Regulation 2017/746)* | CLASS A |

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INNOVATION IN CELLULAR PATHOLOGY

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| DEVICE(S) INFORMATION | | | | |
|---|---|---|---|---|
| **PART NUMBER** | **GTIN** | **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<br>Unit 80, Mochdre Enterprise Park<br>Newtown<br>Powys<br>Mid Wales, UK<br>SY16 4LE |
| Date of Issue | 05/08/2021 |
| Name of Signatory | Hannah Moore |
| Position of Signatory | Product Manager |
| Signature | H Moore<br>H Moore (Aug 5, 2021 13:09 GMT+1) |