

EU DECLARATION OF CONFORMITY – Supa Mega Mother Ship Cassettes

Date: 22/07/2021

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

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|---|---|
| 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 | Histological tissue cassette IVD |
| Product Description | A small device intended to be used in the laboratory to support/contain clinical tissue specimens (e.g., biopsy samples) to facilitate specimen processing [e.g., fixation (encapsulation in paraffin wax), dehydration, infiltration] in preparation for subsequent cytological or histological examination, and storage. It is in the form of a synthetic polymer container, with or without a lid, with drainage holes to maximize fluid exposure during tissue submersion in a parent device into which the container is loaded. This is a single-use device. |
| Product Classification <i>(Classified in accordance with EU Regulation 2017/746)</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 |
|--------------|----------------|------------------|-------------------------------|--------------------|
| EAO-0102-02A | 05056256106411 | 05056256EAO001Z4 | SUPA MEGA MOTHERSHIP – WHITE | 2014 |
| EAO-0104-02A | 05056256106428 | 05056256EAO001Z4 | SUPA MEGA MOTHERSHIP – GREEN | 2014 |
| EAO-0105-02A | 05056256106435 | 05056256EAO001Z4 | SUPA MEGA MOTHERSHIP – GREY | 2014 |
| EAO-0106-02A | 05056256106442 | 05056256EAO001Z4 | SUPA MEGA MOTHERSHIP – BLUE | 2014 |
| EAO-0107-02A | 05056256106459 | 05056256EAO001Z4 | SUPA MEGA MOTHERSHIP – ORANGE | 2014 |
| EAO-0108-02A | 05056256106466 | 05056256EAO001Z4 | SUPA MEGA MOTHERSHIP – PINK | 2014 |
| EAO-0109-02A | 05056256106473 | 05056256EAO001Z4 | SUPA MEGA MOTHERSHIP – YELLOW | 2014 |
| EAO-0110-02A | 05056256106480 | 05056256EAO001Z4 | SUPA MEGA MOTHERSHIP – RED | 2014 |

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 22/07/2021

Name of Signatory Paul Webber

Position of Signatory Joint Managing Director

Signature Paul Webber
Paul Webber (Jul 22, 2021 09:52 GMT+1)

Synergy Number: 01.590.399