

EU DECLARATION OF CONFORMITY – Supa Mega Cassette

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

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

DEVICE(S) INFORMATION				
PART NUMBER	GTIN	UDI-DI	DESCRIPTION	YEAR OF CE MARKING
EAG-0102-02A	05060470561642	05060470EAG001SB	SUPA MEGA CASSETTE - WHITE	2004
EAG-0104-02A	05060470561659	05060470EAG001SB	SUPA MEGA CASSETTE - GREEN	2004
EAG-0105-02A	05060470561666	05060470EAG001SB	SUPA MEGA CASSETTE - GREY	2004
EAG-0106-02A	05060470561673	05060470EAG001SB	SUPA MEGA CASSETTE - BLUE	2004
EAG-0107-02A	05060470561680	05060470EAG001SB	SUPA MEGA CASSETTE - ORANGE	2004
EAG-0108-02A	05060470561697	05060470EAG001SB	SUPA MEGA CASSETTE - PINK	2004
EAG-0109-02A	05060470561703	05060470EAG001SB	SUPA MEGA CASSETTE - YELLOW	2004
EAG-0110-02A	05060470561710	05060470EAG001SB	SUPA MEGA CASSETTE - RED	2004
EAG-0111-02A	05060470561727	05060470EAG001SB	SUPA MEGA CASSETTE - PEACH	2004
EAG-0202-02A	05060470561758	05060470EAG001SB	SUPA MEGA CASSETTE (SLOTTED) - WHITE	2015

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 10:38 GMT+1)