

## **EC Declaration of Conformity**

**to In Vitro Diagnostic Medical Devices (98/79/EC)**

**according to Annex III of the IVDD**

**Serosep Limited,**  
Annacotty Business Park,  
Annacotty,  
Limerick, Ireland.

Declares that HistoPot (also sold under the brand name Histogen) fixative solutions listed below, classified as “all other IVD Medical Devices” conform to the relevant provisions of the EC Council Directive 98/79/EC and are in accordance with Annex III of the IVDD, as implemented by the European Union's Medical Devices Regulations.

Please see [Appendix 1](#) on the next page for product codes and description.

Serosep Limited agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Serosep Limited confirms that no medicinal products/drugs are incorporated in any device covered by the Device Schedule.

**Appendix 1:**

<b><u>Product Code</u></b>	<b><u>Description</u></b>
S10-B-FOR-8ml	Neutral Formalin 10% - 8ml Pot
S10-B-FOR-20ml	Neutral Formalin 10% - 20ml Pot
S10-B-FOR-20ml	Neutral Formalin 10% - 20ml Pot
S10-B-FOR-40ml	Neutral Formalin 10% - 40ml Pot
S10-B-FOR-60ml	Neutral Formalin 10% - 60ml Pot
S10-B-FOR-125ml	Neutral Formalin 10% - 125ml Pot
S10-B-FOR-180ml	Neutral Formalin 10% - 180ml Pot
S10-B-FOR-250ml	Neutral Formalin 10% - 250ml Pot
S10-B-FOR-350ml	Neutral Formalin 10% - 350ml Pot
S10-B-FOR-500ml	Neutral Formalin 10% - 500ml Pot
S10-B-FOR-1000ml	Neutral Formalin 10% - 1000ml Pot
S10-B-FOR-2500ml	Neutral Formalin 10% - 2500ml Pot
S10-B-FOR-5000ml	Neutral Formalin 10% - 5000ml Pot
10-B-FOR-5LJC	Neutral Formalin 10% - 5L Jerrycan
10-B-FOR-10LTC	Neutral Formalin 10% - 10L Polycube
10-B-FOR-20LTC	Neutral Formalin 10% - 20L Polycube

Dated this Thursday, 9<sup>th</sup> November 2017;

  
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