



Serosep Limited,
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Annacotty,
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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.

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.

Signed on behalf of Serosep Limited:

A handwritten signature in blue ink, appearing to read 'Dermot Scanlon', is written over a horizontal line.

Name: Mr. Dermot Scanlon

Title: Managing Director

24th March 2014