Serosep Limited
Annacotty Business Park
Annacotty
Limerick
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Phone 061 358190
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Record number: ECDEC 10

Valid from: 25.02.2016

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

declare under our sole responsibility that the product **HistoPot (also sold under the brand name Histogen) fixative solutions**, 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

Name: Dermot Scanlon
Title: Managing Director
Date: 23.11.2020