



Serosep Limited
Annacotty Business Park
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Record number: ECDEC 11

Valid from: 14.06.2018

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
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Limerick

declares that **EntericBio realtime CPE Panel (EBCPE)**, 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 black ink, appearing to read 'Dermot Scanlon', is written over a horizontal line.

Name: Dermot Scanlon

Title: Managing Director

Date: 18/7/2018