Serosep Limited
Annacotty Business Park
Annacotty
Limerick
Ireland
Phone 061 358190
www.serosep.com

Record number: EUDEC 01

EU Declaration of Conformity

Manufacturer:	**Serosep Limited Annacotty Business Park, Annacotty, Co. Limerick V94 FF83, Ireland (SRN: IE-MF-000020322)**
Notified Body:	**N/A**
Certificate Number:	**N/A**
Catalogue Number/Product Name:	**See Supplement 1**
Device Type:	***In vitro* diagnostic device**
Device Classification:	**Class A (Rule 5)**
Conformity Assessment Route:	**According to Article 48(10): Annex I, II and III of the Regulation (EU) 2017/746**

Standards/Common specifications applied:

I.S EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
I.S. EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
I.S. EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
I.S. EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements
I.S. EN ISO 18113-2:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use

I.S. EN ISO 23640:2015	In Vitro Diagnostic Medical Devices - Evaluation of Stability of in Vitro Diagnostic Reagents
I.S. ISO 6717:2021	In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood

The device(s) named below and covered by the present declaration carry the CE mark and are in conformity with Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro diagnostic medical devices and, if applicable, with any other relevant Union legislation listed above that provides for issuing of an EU declaration of conformity. This declaration of conformity is issued under the sole responsibility of the manufacturer, Serosep Limited.

Susan Dwane

Signed for on behalf of Serosep Limited
Name: **Susan Dwane**
Function of person: **Regulatory Manager/PRRC**
Place and date of declaration: **Limerick, Ireland, 05 Aug 2022**

Supplement 1 to Declaration of Conformity – In Vitro Diagnostic Device

EMDN Code	Basic UDI-DI	Catalogue #	Product Name	Risk Class	Intended Purpose
W01030704	053 915 1387 HIST ZN	S10-B-FOR-40ML	HistoPot 40ml	A	For in vitro diagnostic use. The HistoPot 10% neutral buffered formalin specimen container is intended for use as a fixative in the processing of biological tissues or clinical samples. Containers with 10% buffered neutral Formalin for histological samples are used in clinical and histopathological laboratories for in vitro diagnostics. Tissue samples taken from patients are placed in containers with 10% buffered neutral formalin. HistoPot formalin containers are designed for convenient transportation and fixation of samples of biological tissues or clinical samples of a patient for subsequent processing and analysis in a
		S10-B-FOR-40TRAY	HistoPot 40ml Tray		
		S10-B-FOR-60ML	HistoPot 60ml		
		10-B-FOR-60MLRC	HistoPot 60ml Red Cap		
		S10-B-FOR-60ML-ASZ	HistoPot 60ml		
		S10-B-FOR-60TRAY	HistoPot 60ml Tray		
		S10-B-FOR-125ML	HistoPot 125ml		
		S10-B-FOR-125TRAY	HistoPot 125ml Tray		
		S10-B-FOR-180ML	HistoPot 180ml		
		S10-B-FOR-250ML	HistoPot 250ml		
		S10-B-FOR-350ML	HistoPot 350ml		
		S10-B-FOR-500ML	HistoPot 500ml		
		S10-B-FOR-500ML T/P	HistoPot 500ml		

		S10-B-FOR-1000ml	HistoPot 1000ml		histopathological laboratory.
		S10-B-FOR-1L	HistoPot 1L		
		S10-B-FOR-2.5LT/P	HistoPot 2.5L		
		S10-B-FOR-5LT/P	HistoPot 5L		
		S10-B-FOR-10L	HistoPot 10L		
		S10-B-FOR-20L	HistoPot 20L		
		S10-B-FOR-5LJC	HistoPot 5L Jerrycan		
		10-B-FOR-10LTC	HistoPot 10L Polycube		
		10-B-FOR-20LTC	HistoPot 20L Polycube		