

Declaration of Conformity

Product Name	CytoSep™		
Intended Purpose	hold biological fluids for further In Vitro diagnostic		
Product Codes	M963; M964; M965; M966; M967; M968 Series		
Basic UDI-DI	667243		
Manufacturer	Simport Scientific Inc. 2588 Bernard-Pilon Beloil Quebec J3G 4S5 Canada		
Authorized Representative in Europe	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="text-align: center; width: 40px; height: 40px;">EC</td> <td style="text-align: center; width: 40px; height: 40px;">REP</td> </tr> </table> <p style="margin-left: 20px;">EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands</p> <p style="margin-left: 20px;">SRN NL-AR-000000116</p>	EC	REP
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Simport declares that the above-mentioned products meet the provision of the Regulation (EU) 2017/746 of the European Parliament and of the Council on *In Vitro* Diagnostic Medical Devices and Regulation (EU) 2017/746 as transposed in the national laws of the Member States:

- That the products have been classified as general IVD and Rule 5(c), class A (Low Individual Risk and Low Public Health Risk);
- That the products listed above are in conformity with the Annex II (Essential Requirements) and III of Regulation (EU) 2017/746
- That the products do not contain medicinal substances;
- That the products do not contain animal tissues.



Annette Roy, Regulatory and Technical Support
Place and Date: Beloil, June 16, 2022