Simport Scientific inc.
Since 1975
A family owned Canadian company

CE

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 Beloeil Quebec J3G 4S5 Canada
Authorized Representative in Europe	EC REP EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands SRN NL-AR-000000116

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: Beloeil, June 16, 2022