



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 SRN NL-AR-C | REP | EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands |

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