Simport Scientific inc.
Since 1975
A family owned Canadian company

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Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Simport Scientific Inc.	2588 Bernard-Pilon, Beloeil, Quebec, J3G 4S5, Canada	CA-MF-000045478

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/email**
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**
Cytology Funnels	See Appendix I - List of Trade Names and Product Reference Codes	667243CytologyD3
Intended Purpose		**Photo**
CytoSep™ cytology funnels are designed to hold Biological fluids for centrifugation, to allow cells to be concentrated onto a microscope slide for the preparation of samples and further analysis. It is a non-automated, single use device for in vitro diagnostics. Not automated, not a qualitative, semi-quantitative or quantitative device.		N/A

IVDR RISK CLASS / COMMON SPECIFICATIONS		
Device Classification		**Common Specifications**
Class	A	Holding Biological fluids for centrifugation, to allow cells to be concentrated onto a microscope slide for the preparation of samples and further analysis.
Rule	5(c)	

Simport Scientific Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

- In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746

COMPANY REPRESENTATIVE: Claudine Lafond

TITLE: Vice-President **SIGNATURE:**

PLACE: Beloeil, Canada **DATE:** 14/07/2025

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Appendix I - List of Trade Names and Product Reference Codes

The following products are included under this Declaration of Conformity and comply with the relevant provisions of the applicable regulations:

M963 Series - SAKURA CYTO-TEK® Components

- **M963B** - Base Holder for M963-1 SAKURA CYTO-TEK® Fluid Chamber
- **M963C** - Cap for M963-1 SAKURA CYTO-TEK® Fluid Chamber
- **M963FW** - White Filter Card for SAKURA CYTO-TEK® Cytology Funnel
- **M963-1** - Fluid Chamber for SAKURA CYTO-TEK® Cytocentrifuge

M964 Series - CYTOSEP™ Single Funnel Components

- **M964-10FW1** - Individually Wrapped CYTOSEP™ Single Funnel with White Filter Paper & Cap
- **M964B** - CYTOCLIP Funnel Clip
- **M964-10FT** - CYTOSEP™ Single Funnel / Brown Filter Paper & Cap
- **M964-1** - CYTOSEP™ Single Funnel Only
- **M964-20FW1** - Individually Wrapped CYTOSEP™ Double Funnel / White Filter Paper & Cap
- **M964-1D** - CYTOSEP™ Double Funnel Only
- **M964-10FW** - CYTOSEP™ Single Funnel with White Filter Paper & Cap
- **M964-20FW** - CYTOSEP™ Double Funnel / White Filter Paper & Cap
- **M965C** - CYTOSEP™ Cap Only for M964-M965

M965 Series - CYTOSEP™ Double Funnel Components

- **M965B** - CYTOSEP™ Base Holder for M965-1 & M965-1D
- **M965C** - CYTOSEP™ Cap Only for M964-M965
- **M965FW** - White Filter Paper for CYTOSEP™ Single Funnel
- **M965FT** - Brown Filter Paper for CYTOSEP™ Single Funnel
- **M965FWD** - White Filter Paper for Double CYTOSEP™ Funnel
- **M965-10FT** - CYTOSEP™ Single Funnel with Brown Filter Paper & Cap
- **M965-1** - CYTOSEP™ Single Funnel Only
- **M965-1D** - CYTOSEP™ Double Funnel Only
- **M965-20FW** - Double CYTOSEP™ Cytology Funnel with White Paper & Cap
- **M965-10FW** - CYTOSEP™ Single Funnel with White Filter Paper & Cap
- **M965-40** - CYTOSEP™ Mega Funnel & Cap
- **M965FWDV** - White Paper Filter for TPX Double Funnel

M966 Series - HETTICH CYTO-SYSTEM Components

- **M966-2** - One-Funnel Chamber, 2ml for HETTICH CYTO-SYSTEM
- **M966-4** - One-Funnel Chamber, 4ml for HETTICH CYTO-SYSTEM
- **M966-8** - One-Funnel Chamber, 8ml for HETTICH CYTO-SYSTEM
- **M966FW** - White Filter Card for HETTICH 1 to 4ml Chambers
- **M966FW8** - White Filter Card for HETTICH 8ml Chambers
- **M966-1** - One-Funnel Chamber, 1ml for HETTICH CYTO-SYSTEM

M967 Series - WESCOR & ELITECH Components

- **M967FWD** - White Filter Paper for WESCOR Double Funnel
- **M967FW** - White Filter Paper for ELITECH Single Funnel
- **M967-10FW** - Single Sample Chamber with White Filter Paper & Cap
- **M967-20FW** - Double Sample Chamber with White Filter Paper & Cap

M968 Series - STATSPIN Components

- **M968FW** - White Filter Card for STATSPIN Single Funnel
- **M968-1** - CYTOSEP™ Cell Concentrator

M984 Series - EZ SHANDON CYTOCENTRIFUGE Components

- **M984-10FW** - CYTOSEP EZ SHANDON CYTOCENTRIFUGE SINGLE FUNNEL WHITE FILTER & CAP 0.1 TO 0.5ML
- **M984-20FW** - CYTOSEP EZ SHANDON CYTOCENTRIFUGE DOUBLE FUNNEL WHITE FILTER & CAP 0.05 TO 0.25ML
- **M984-30M** - CYTOSEP EZ SHANDON CYTOCENTRIFUGE MEGA FUNNEL &CAP 0.5ML TO 6.0 ML
- **M984FW10** - White Filter Paper for CYTOSEP EZ SHANDON Single Funnel
- **M984FW20** - White Filter Paper for CYTOSEP EZ SHANDON Double Funnel

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Appendix II: Revision History Table

Rev	Revision Date	Description of Change	Originator
1.0	03/05/2022	Initial Release – Declaration of Conformity	Annette Roy
1.1	19/09/2024	Addition of Appendix I: Addendum to the Original Declaration of Conformity	Rossano Morgan-Cavallaro
1.2	01/10/2025	The Addition of Appendix I – List of Trade Names and Product Reference Codes and it's alignment with the Product Listing Addendum.	Rossano Morgan-Cavallaro
1.3	16/04/2025	Reformatted to EMERGO template with Revision History Table. No change to Declaration content.	Rossano Morgan-Cavallaro
	14/07/2025	Minor Update - Followed Emergo's expert recommendation to remove "Used by laboratory professionals only" from the Intended Purpose Statement. In addition, added the M984FW10 & M984FW20 to the M984 Series, which should have been included in previous update.	Rossano Morgan-Cavallaro

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