

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Name	Model/Number
Cryogenic Vials (Cryovial™)	See Appendix II - List of Trade Names and Product Reference Codes

MANUFACTURER		
Name of Company	Address	Representative
Simport Scientific Inc.	2588 Bernard-Pilon Beloeil Quebec J3G 4S5 Canada	Isabelle Déry ISO Facilitator & Logistic Coordinator

AUTHORIZED REPRESENTATIVE		
Name of Company	Address	Telephone/Email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

CONFORMITY ASSESSMENT		
Device Classification	Route to Compliance	Standards Applied
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	

Simport Scientific Inc. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Claudine Lafond

TITLE: Vice-President

SIGNATURE:



PLACE: Beloeil, Canada

DATE: 03/05/2022

Appendix I: Addendum to the Original Declaration of Conformity

Per 31 January 2023, the address of our EU Authorized Representative as listed on the original DoC has changed.

OLD ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

NEW ADDRESS AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

DATE: 01/03/2023

COMPANY REPRESENTATIVE: Claudine Lafond

TITLE: Vice-President

SIGNATURE:



DATE: 19/09/2024

Appendix II - 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 Directive 98/79/EC:

T210 Series - CRYOGENIC 2D VIALS

- **T210-2A** - Cryogenic 2D Vials Tubes & Closures (500/Cs)
- **T210-2A81B** – Pre-Racked Tubes (10/Cs)

T301 Series - CRYOVIAL® Internal Thread with Silicone O-Ring Seal

- **T301-1** – CRYOVIAL® 1.2 ml self-standing
- **T301-2** – CRYOVIAL® 2 ml self-standing
- **T301-3** – CRYOVIAL® 2 ml round bottom
- **T301-4** – CRYOVIAL® 4 ml round bottom
- **T301-4A** – CRYOVIAL® 4 ml self-standing
- **T301-5** – CRYOVIAL® 5 ml round bottom

T308 Series - CRYOVIAL® External Thread with Lip and Silicone Washer Seal

- **T308-1A** – CRYOVIAL® 1.2 ml self-standing
- **T308-2** – CRYOVIAL® 2 ml round bottom
- **T308-2A** – CRYOVIAL® 2 ml self-standing
- **T308-3A** – CRYOVIAL® 3 ml self-standing
- **T308-4A** – CRYOVIAL® 4 ml self-standing
- **T308-5A** – CRYOVIAL® 5 ml self-standing

T309 Series - CRYOVIAL® External Thread with Lip Seal

- **T309-1A** – CRYOVIAL® 1.2 ml self-standing
- **T309-2** – CRYOVIAL® 2 ml round bottom
- **T309-2A** – CRYOVIAL® 2 ml self-standing
- **T309-3A** – CRYOVIAL® 3 ml self-standing
- **T309-4A** – CRYOVIAL® 4 ml self-standing
- **T309-5A** – CRYOVIAL® 5 ml self-standing

T310 Series - CRYOVIAL® External Thread with Silicone Washer Seal

- **T310-1A** – CRYOVIAL® 1.2 ml self-standing
- **T310-2** – CRYOVIAL® 2 ml round bottom
- **T310-2A** – CRYOVIAL® 2 ml self-standing
- **T310-3A** – CRYOVIAL® 3 ml self-standing
- **T310-4A** – CRYOVIAL® 4 ml self-standing
- **T310-5A** – CRYOVIAL® 5 ml self-standing
- **T310-10A** – CRYOVIAL® 10 ml self-standing

T311 Series - CRYOVIAL® Internal Thread with Silicone Washer Seal

- **T311-1** – CRYOVIAL® 1.2 ml self-standing
- **T311-2** – CRYOVIAL® 2 ml self-standing
- **T311-3** – CRYOVIAL® 2 ml round bottom
- **T311-4** – CRYOVIAL® 4 ml round bottom
- **T311-4A** – CRYOVIAL® 4 ml self-standing
- **T311-5** – CRYOVIAL® 5 ml round bottom

Appendix III: 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 II – List of Trade Names and Product Reference Codes and it's alignment with the Product Listing Addendum.	Rossano Morgan-Cavallaro
1.3	30/03/2025	Reformatted to EMERGO template with Revision History Table. No change to Declaration content.	Rossano Morgan-Cavallaro