

## 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 Beloil 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:** Beloil, 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.

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

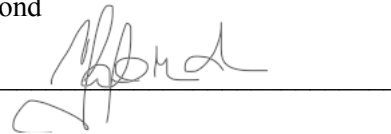
<b>NEW ADDRESS AUTHORIZED REPRESENTATIVE</b>		
<b>Name of company</b>	<b>Address</b>	<b>Telephone/email</b>
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	+31.70.345.8570 - phone EmergoEurope@ul.com

**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