

# Certificate of Analysis



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## Product Details

**Product description:** Warming Set  
**Product code:** WRM-01  
**Lot number:** J000006869  
**Expiry date:** 20 Aug. 2025

## Intended Use

Warming Set and its individual solutions (WarmSol 1, WarmSol 2, WarmSol 3) is used for the warming of embryos that have undergone vitrification using the Vitrification Set (VIT-01) or Gavi Medium Cartridge (GAVI-MED-20). WarmSol 1, WarmSol 2 and WarmSol 3 should not be used individually, always use as part of the Warming Set.

**USA only:** Gems Warming Set is used for the warming of human blastocyst stage embryos that have undergone vitrification. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician or practitioner trained in its use.

## Set Contents

The Gems Warming set comprises of WarmSol 1, WarmSol 2, and WarmSol 3, all supplemented with human serum albumin.

## Product Analysis

Assay	Specification			Result
	WarmSol 1	WarmSol 2	WarmSol 3	
pH at 25 °C in air	7.3 – 7.5			Pass
Osmolality	1280 - 1320 mOsm/kg	780 - 820 mOsm/kg	295 - 305 mOsm/kg	Pass
MEA	MEA (1-cell): ≥80% developed to blastocyst stage or beyond by 96 hours			Pass
Endotoxin	<0.40 EU/mL			Pass
Sterility	No Growth			Pass
HSA Analysis	15.00 – 25.00 mg/mL			Pass

## Product passed and released by Quality

**Signature:**  Electronically signed by: Lalitha Kalyanaraman  
Reason: QA Approval  
Date: Oct 18, 2024 10:12 GMT+11

**Name:** Lalitha Kalyanaraman

**Job Title:** QA Associate

**Date:** 18 Oct. 2024







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Final Audit Report

2024-10-18

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