



Blood Cell Storage, Inc.
4203 23rd Ave W.
Seattle WA, 98199 USA

Certificate of Compliance

Date of EtO Processing: 30 June 2021

Product Name: SAFE Sens[®] sv² sensor kit

Part Number: 400016

Lot Number: 2105031

Storage: Room temperature protected from light

EXPIRY: 29 February 2024

BCSI certifies that the above referenced product:

- Was tested by BCSI whose Quality Management System is approved by an accredited registering body to the ISO 9001:2015 Quality Systems Standard and ISO 13485:2016 Medical Devices Quality Management System.
- Was tested in accordance with applicable BCSI Standard Procedures.
- Was tested and complies with visual and performance specifications as specified in the product specification, including:

- | | |
|--|--------------|
| ✓ Mouse embryo toxicity | Pass |
| ✓ Biological Indicator Culturing Test | Pass |
| ✓ EtO Sterilized (SAL 10 ⁻⁶) | Pass |
| ✓ Precise pH interpretation, encrypted pHID
(when used at 35°-38°C) | PA3!5 |



Steve Geelhood
Business Director

23 Feb 22

Date

BCSI Reference: 2202041

Rev 400016.02

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