



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

# Certificate of Compliance

Date of EtO Processing: 26 March 2021

Product Name: SAFE Sens<sup>®</sup> sv<sup>2</sup> sensor kit

Part Number: 400016

Lot Number: 2102026

Storage: Room temperature protected from light

EXPIRY: 31 May 2023

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 <sup>-6</sup> )	Pass
✓ Precise pH interpretation, encrypted pHID (when used at 35°-38°C)	<b>!1K24</b>



  
\_\_\_\_\_  
Steve Geelhood  
Business Director

20 Jul 2021  
\_\_\_\_\_  
Date

BCSI Reference: 2107027

Rev 400016.02

THIS DOCUMENT IS PROPRIETARY AND ITS CONTENTS ARE THE EXCLUSIVE PROPERTY OF BCSI.  
THIS DOCUMENT MAY NOT BE ALTERED IN ANY FORM WHATSOEVER, WITHOUT PRIOR WRITTEN  
PERMISSION FROM BCSI'S QUALITY ASSURANCE MANAGER.

