



Blood Cell Storage, Inc.
 123 NW 36th Street, Suite 220
 Seattle, WA 98107
 USA

Certificate of Compliance

Date of EtO Processing: 21 August 2020

Product Name: SAFE Sens[®] sv² sensor kit

Part Number: 400016

Lot Number: 2005001

Storage: Room temperature protected from light

EXPIRY: 31 December 2022

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)	PAGCT





 Irena Dikovsky
 Director of Quality

10 Mar 2021

 Date

BCSI Reference: 2103011

Rev 400016.01

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.

