

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

Quality

ISO 13485

## Certificate of Compliance

Date of EtO Processing: 26 March 2021

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

Part Number: 400010

Lot Number: 2102032

Storage: Room temperature protected from light

EXPIRY: <u>30 April 2023</u>

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.
- 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) 7HKWA

Irena Dikovsky
Director of Quality

Date

BCSI Internal Tracking: 2105001

400010.04

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.

