

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

Certificate of Compliance

Date of Manufacture: 15 September, 2020

Product Name: SAFE SensTM sv²

Part Number: 400009

Lot Number: 1911001

Storage: Room temperature protected from light

EXPIRY: 28 February, 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.
- 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

✓ Non-pyrogenic (LAL test)

Pass

Quality

DEKR/

ISO 13485

✓ EtO Sterilized (SAL 10⁻³)

Pass

✓ Precise pH interpretation, encrypted pHID **T0\$FO** (when used at 35°-38°C)

Irena Dikovsky

BCSI

Director of Quality

Date

BCSI Internal Tracking: 2009011

Rev.03

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.