

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

> Quality ISO 13485

Certificate of Compliance

Date of EtO Processing: 26 March 2021

Product Name: SAFE Sens® sv² sensor kit

Part Number: 400003

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.

• 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

= 1010 Brown minutes outland 1 000

✓ EtO Sterilized (SAL 10⁻⁶)

Pass

Pass

✓ Precise pH interpretation, pHID

C6852

(when used at 35°-38°C)

Irena Dikovsky Director of Quality Date

BCSI Internal Tracking: 2105043

400003.05

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.

