

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

> Quality ISO 13485

DEKRA

## Certificate of Compliance

Date of Manufacture: 14 July, 2020

Product Name: SAFE Sens<sup>TM</sup> sv<sup>2</sup>

Part Number: 400003

Lot Number: 1910011

Storage: Room temperature protected from light

EXPIRY: \_\_31 December, 2021

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

✓ EtO Sterilized (SAL 10<sup>-3</sup>)

Pass

✓ Precise pH interpretation, pHID

C6168

(when used at 35°-38°C)

Irena Dikovsky

Director of Quality

BCSI Internal Tracking: 2007009

Rev.04

14 Jul 2020

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