

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

Quality

DEKRA

ISO 13485

Certificate of Compliance

Date of Manufacture: 05 March, 2020

Product Name: SAFE SensTM sv²

Part Number: 400009

Lot Number: 1910004

Storage: Room temperature protected from light

EXPIRY: __31 July, 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 10⁻³)

Pass

✓ Precise pH interpretation, encrypted pHID **8%F#R** (when used at 35°-38°C)

Irena Dikovsky Director of Quality

BCSI

Date

BCSI Internal Tracking: 2003004

Rev.03

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