

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

> Quality ISO 13485

ISO 9001

DEKRA

Certificate of Compliance

Date of Manufacture: 16 March, 2020

Product Name: SAFE SensTM sv²

Part Number: 400003

Lot Number: 1910004

Storage: Room temperature protected from light

EXPIRY: <u>31 July, 2021</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

✓ Non-pyrogenic (LAL test)

Pass

✓ EtO Sterilized (SAL 10⁻³)

Pass

✓ Precise pH interpretation, pHID (when used at 35°-38°C)

93751

Irena Dikovsky

Director of Quality

16 Mar 2020

Date

BCSI Internal Tracking: 2003014

Rev.04

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