

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

Quality

DEKR/

ISO 13485

## Certificate of Compliance

Date of Manufacture: 19 August, 2020

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

Part Number: 400003

Lot Number: 1910026

Storage: Room temperature protected from light

EXPIRY: <u>31 January</u>, 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

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

Pass

✓ Precise pH interpretation, pHID **E0571** (when used at 35°-38°C)

Irena Dikovsky Director of Quality Date

BCSI Internal Tracking: 2008013

Rev.04

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