

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

> Quality ISO 13485

DEKRA

Certificate of Compliance

Date of EtO Processing: 21 August 2020

Product Name: SAFE Sens® sv² sensor kit

Part Number: 400003

Lot Number: 1912015

Storage: Room temperature protected from light

EXPIRY: ___30 April 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

✓ Biological Indicator Culturing Test

Test Pass

✓ EtO Sterilized (SAL 10⁻⁶)

Pass

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

Irena Dikovsky Director of Quality 1 TNOV 10

Date

BCSI Internal Tracking: 2011017

400003.05

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