

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

Certificate of Compliance

Date of EtO Processing:	21 August 2020
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Product Name: sv² sensor kit

Part Number: 400019

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 and ISO 13485:2016 Medical Devices Quality Management System.

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

Pass

✓ EtO Sterilized (SAL 10⁻⁶)

Pass

✓ Precise pH interpretation, encrypted pHID

^%@OM

Quality

DEKRA

ISO 13485

www.dekra-seal.co

(when used at 35°-38°C)

Irena Dikovsky Director of Quality

BCSI Reference: 2011022

Rev 400019.02

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