

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

Certificate of Compliance

Date of EtO Processing: 26 March 2021

Product Name: sv² sensor kit.

Part Number: 400019

Lot Number: 2102032

Storage: Room temperature protected from light

EXPIRY: 30 April 2023

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

Quality

DEKRA

ISO 13485 ISO 9001

✓ Biological Indicator Culturing Test

Pass

✓ EtO Sterilized (SAL 10⁻⁶)

Pass

✓ Precise pH interpretation, encrypted pHID

5@IF6

(when used at 35°-38°C)

Irena Dikovsky Director of Quality

BCSI Reference: 2105015

Rev 400019.02

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