



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: SAFE Sens[®] sv² sensor kit

Part Number: 400016

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
 - ✓ Biological Indicator Culturing Test Pass
 - ✓ EtO Sterilized (SAL 10⁻⁶) Pass
 - ✓ Precise pH interpretation, encrypted pHID 2ZQ=1
(when used at 35°-38°C)



Irena Dikovskiy
Director of Quality

04 May 2021
Date

BCSI Reference: 2105002

Rev 400016.01

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