



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

# Certificate of Compliance

Date of Manufacture: 01 August, 2019

Product Name: sv<sup>2</sup> sensor kit

Part Number: 400016

Lot Number: 1904016

Storage: Room temperature protected from light

EXPIRY: 01 January, 2021

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         |
| ✓ Non-pyrogenic (LAL test)   | Pass         |
| ✓ EtO Sterilized (SAL 10 <sup>-3</sup> )                               | Pass         |
| ✓ Precise pH interpretation, encrypted pHID<br>(when used at 35°-38°C) | <b>P!OU4</b> |



Irena Dikovskiy  
 Director of Quality

Date

BCSI Reference: 1908008

Rev 400016.00

THIS DOCUMENT IS PROPRIETARY AND ITS CONTENTS ARE THE EXCLUSIVE PROPERTY OF BCSI.  
 THIS DOCUMENT MAY NOT BE ALTERED IN ANY FORM WHATSOEVER, WITHOUT PRIOR WRITTEN  
 PERMISSION FROM BCSI'S QUALITY ASSURANCE MANAGER.

