



# Certificate of Compliance

Date of Manufacture: 18 March, 2020

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

Part Number: 400019

Lot Number: 1910004

Storage: Room temperature protected from light

EXPIRY: 31 July, 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>-6</sup> )                               | Pass         |
| ✓ Precise pH interpretation, encrypted pHID<br>(when used at 35°-38°C) | <b>X6H2Z</b> |



Irena Dikovsky  
Director of Quality

Date

BCSI Reference: 2003024

Rev 400019.01

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