



Certificate of Compliance

Date of Manufacture: 26 May, 2020

Product Name: sv² 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 ⁻⁶) | Pass |
| ✓ Precise pH interpretation, encrypted pHID
(when used at 35°-38°C) | X6H2Z |



Irena Dikovsky
Director of Quality

26 May 2020

Date

BCSI Reference: 2005022

Rev 400019.01

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