

Certificate of Compliance

Date of EtO Processing: 06 February 2023

Product Name: sv² sensor kit

Part Number: 400019

Lot Number: 2208013

Storage: Room temperature protected from light

EXPIRY: __31 May 2025

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

0=YJC

(when used at 35°-38°C)

Steve Geelhood Business Director

Date

BCSI Reference: 2305035

Rev 400019.04

Quality

DEKRA

ISO 13485 ISO 9001

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