

Certificate of Compliance

Date of EtO Processing: 26 March 2021

Product Name: sv² sensor kit

Part Number: 400019

Lot Number: 2012001

Storage: Room temperature protected from light

EXPIRY: <u>31 July 2023</u>

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 @0C98 (when used at 35°-38°C)

Steve Geelhood Business Director 205-1 2021 Date

BCSI Reference: 2107028

Rev 400019.03

Quality ISO 13485

DEKRA

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.

