Quality 190 13485

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Certificate of Compliance

Date of EtO Processing: 06 February 2023

Product Name: SAFE Sens® sv² sensor kit

Part Number: 400016

Lot Number: 2208012

Storage: Room temperature protected from light

EXPIRY: 30 April 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
-	Widuse cilibiyo toxicity	1 ac

✓ Biological Indicator Culturing Test Pass

✓ EtO Sterilized (SAL 10⁻⁶) Pass

✓ Precise pH interpretation, encrypted pHID ^AOLY (when used at 35°-38°C)



I approve this document 04 January 2024 | 11:45:40 AM PST

04 January 2024

Hannah Erickson Quality Assurance Date

BCSI Reference: 2401009 Rev 400016.03

