

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

✓ Biological Indicator Culturing Test Pass

✓ EtO Sterilized (SAL 10⁻⁶) Pass

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

Quality Assurance

11 Sep 2023

BCSI Reference: 2309003

Rev 400016.03

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.

