Certificate of Compliance

LOT #	EXPIRATION DATE	PRODUCT IDENTIFICATION
G23571	12-2026	Item # 8497

Quality Management System – Complies with the current version of the EN ISO 13485 Standard.

BSE/TSE – Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Non-Pyrogenic – Tested and met the criteria established in the current version of ANSI/AAMI ST 72, "Bacterial Endotoxins – Test methodologies, routine monitoring, and alternatives to batch testing". The acceptance level for product is ≤ 0.02 EU/mL or ≤ 0.8 EU/device.

USP Class VI Testing – All material resin is tested, qualified and shown to be non-toxic as established in the Standard USP Class VI Chapter <87>, "Biological Reactivity Tests, In Vitro" and Chapter <88>, "Biological Reactivity Tests, In Vivo."

Human DNA Free – Tested by PCR method and found to be free of detectable human DNA contamination. The assay detection limit is 5 pg.

PCR Inhibition – Tested with real time Polymerase Chain Reaction and found no inhibition of real time PCR with a Ct comparison of ≤.5X$CT_{PosCtrl}$-Ct.

DNase/RNase Free – Tested by nuclease assay and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-5} Kunitz units/μL for DNase and 10^{-9} Kunitz units/μL for RNase.

Sterilization – Products that have been provided as sterile have been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137-3, "Sterilization of health care products - Radiation". Products meet a minimum Sterility Assurance Level (SAL) of 10^{-3}.

Quality Control Testing – Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspection and inline tests are: Visual Inspection – Pass, Dimensional Inspection – Pass, Functional Test – Pass, Accuracy Test – Pass. This product met Sorenson BioScience's high standards of quality at the time of batch/lot release.

Composition – Our products are made with 100% research grade virgin polypropylene of the highest purity and quality. Our material suppliers do not use or intentionally incorporate agents into the raw materials used in our products, which include but are not limited to the following:

- Slip Agents (including oleamide, erucamide, stearamide)
- Biocides (including di(2-hydroxyethyl)methyldodecyl ammonium salts (DiHEMDA))
- Plasticizers (softeners/phthalates)
- Latex
- Metallic Dyes
- Glucan
- Cellulose

Name: _____ **Date:** 25 January, 2024

Position: Quality Manager

DOMINIQUE DUTSCHER SAS