



Certificate of Product Conformity and Compliance

Aspen Surgical Products, Inc certifies that all products pertaining to the lot(s) included in this shipment been manufactured, packaged, assembled, labeled, inspected, and tested in full accordance with all applicable internal and customer specifications, in compliance with FDA 21CFR 820, UDI requirements, ISO 13485, MDD 93/42/EEC, MDR 2017/245, ANVISA, SOR 98-282, MHLW Ordinance 169, as applicable.

Products which are identified as sterile are in compliance with the applicable ISO standard as shown below and sterility assurance level, SAL 10(-6), has been achieved. Sterile packaging integrity has been demonstrated to be maintained throughout the entire shelf life, as long as the package is not damaged or opened. If no expiration date is noted, the products are provided non-sterile or have no shelf life limitations.

- Product sterilized using Gamma Radiation was sterilized in compliance with EN ISO 11137 (Radiation Sterilization Requirements for Development, Validation and Routine Control).
- Product Sterilization using Ethylene Oxide was sterilized in compliance with EN ISO 11135 (Ethylene Oxide Sterilization Requirements for Development, Validation and Routing Control).

Lot Number	Part Number	Description	Expiration Date	Sterilization Method	Notes (if applicable)
479031	1400-20-VWC	Vwr 52877-310 - Custom Black Lab Marker W/ Fine Tip - Nonsterile	N/A	Non-Sterile	

Certified By : Michelle Pulaski
Name

Sr Manager QA
Title

10/6/2025
Date