



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, CMCAS, 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	Customer Part Number	Part Description	Quantity	Expiration Date	Sterilization Method	PO/ Customer Order #	Notes (if applicable)
402489	1400-13-VWC	1400-13-VWC	Vwr 52877-355 - Custom Blue Lab Marker W/ Fine Tip - Nonsterile (10/box)	40	N/A	Non-Sterile	4517160367 / C1336786	

Certified By :

Michelle Ruback

Name

Sr Manager QA

Title

8/5/2024

Date