Aspen Surgical

Certificate of Compliance

Aspen Surgical hereby certifies that all products identified below have been manufactured in accordance with the current FDA Quality System Regulation 21 CFR Part 820, Medical Device Directive 93/42/EEC, Medical Device Quality Management System EN ISO 13485, and Canadian Medical Device Regulation SOR/98-282.

Quality Control Testing – Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and signed off by qualified personnel for product release.

Sterilization – All products which are labeled as sterile and released for sale by Aspen Surgical are certified to be sterile as long as the package is unopened and undamaged. Sterilization cycle development / validation has been performed in accordance with current ANSI/AAMI/ISO guidelines.

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

Device Listing / Manufacturing Site Registration / Pre-Market Notification: Medical devices are listed with FDA per 21 CFR 807. Manufacturing sites are registered with FDA per 21 CFR 807. The devices satisfy FDA pre-market notification requirements per 21 CFR 807.

Item Number & Description	Lot Number	Method of Sterilization
1400-20-VWC VWR 52877-310 - Custom Black Lab Marker W/ Fine Tip - Nonsterile (10/box)	183406	Non-Sterile

Certified by: Kath Nap — Name; Quality Specialist — Title; 18 Feb 2019 — Date

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