CooperSurgical

Certificate of Analysis / Conformity

The Products indicated below have been sterilized using Ethylene Oxide gas. The sterilization process has been demonstrated to meet the requirements of **CooperSurgical Inc** process specifications, AAMI/ISO 11135, and ISO 10993 Part 7 limits of ethylene oxide residuals.

These Medical devices are certified as sterile and conform to all documented manufacturing specifications and requirements.

Product: 0105173322 **Lot number:** 1206 **Expiration Date:** 2023-06-25

Sterilization:

SS Load Number: 18211 - 01031. CSI Sterilization load number: WSL-0718-01.

Sterilization Cycle Specification Number: 91.

MEA testing: is considered acceptable if:

- Needle range: Cell 2 MEA need to be >80%, Cell 1 MEA need to be >70%.
- Catheter Range: Cell 2 MEA must be >80%.

MEA Product results: 100 % (2 cell test)
100 % (1 cell test)

LAL testing: is considered acceptable if:

- Pyrogen test results must be less than or equal to 20 EU/device for Dual Lumen product.
- The remainder of products such as Oocyte Needle, ET Catheter and Sure Pro the pyrogen results must be less than or equal to 0.5 EU/ device.

LAL Product results: 0.5 EU/device

PRODUCT FINAL RELEASE

I hereby certify that all activities defined in the DMR have been completed and the associated date and documentation have been reviewed are satisfactory and the product meets all defined acceptance criteria. This product may therefore be released for commercial distribution on behalf of the design authority.

DVangas
Signature

08/Ago/18.
Date

Refer to document SOP-0048 for process overview