



April 1, 2016

Subject: Gulf Fiberoptics Fiber Optic Cable Compatibility with the STERIZONE® VP4 Sterilizer

Dear valued Gulf Fiberoptics customer:

Gulf Fiberoptics, in cooperation with TSO₃'s Compatibility Testing Services, has completed sterilization verification, material and functionality evaluations of the Gulf Fiberoptics Fiber Optic Cable product family.

The studies were performed with guidance provided in:

- ANSI/AAMI/ISO 14937:2009 *Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.*
- AAMI TIR12:2010 *Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.*
- AAMI TIR39:2009 *Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices.*

Sterilization efficacy studies demonstrate that if a Gulf Fiberoptics Fiber Optic Cable is sterilized in accordance with the STERIZONE® VP4 Sterilizer recommendations, Fiber Optic Cable reprocessed in STERIZONE® VP4 Sterilizer will be sterile to a sterility assurance level (SAL) of 10^{-6} .

Should you have any further questions regarding this subject or require additional assistance, please feel free to contact Gulf Fiberoptics at +1 813.855.6618, contact@gulffiberoptics.com, or contact one of its authorized distributors.

Sincerely,

A handwritten signature in black ink, appearing to read "Craig Vogeley", is written over a horizontal line.

Craig Vogeley
Vice President, Operations