

**TEST ARTICLE NAME**

HARD CLAD OPTICAL FIBER

**SPONSOR**

Frank Fontan  
Fiberguide Industries, Inc.  
1 Bay Street  
Stirling, NJ 07980

**TEST ARTICLE IDENTIFICATION**

Lot: B042409A-1

**TEST ARTICLE RECEIVED**

May 26, 2009

**STUDY TITLE**

Ethylene Oxide Exposure

**METHOD**

The test article was exposed to a targeted 600 mg per liter EO cycle\* under the following conditions:

Cycle Number:	09S-0527-1
Prevacuum:	1.45 psia
Humidification Injection Time:	5.48 minutes
Humidification Dwell Time:	30 minutes
Initial R.H. Dwell Vacuum:	1.62 psia
Post R.H. Dwell Vacuum:	2.97 psia
Target Relative Humidity:	60% R.H.
Calculated Relative Humidity:	61% R.H.
Sterilant Charge Set Point:	26.68 psia
Actual Sterilant Pressure:	26.78 psia
EO Concentration:	602 mg/L
Chamber Temperature Set Point:	54.4°C
Actual Chamber Temperature:	54.5°C
Exposure Time:	120 minutes
Postvacuum:	1.45 psia
Air Wash(s):	5
Aeration:	0.25 minutes

\*Ethylene oxide, Oxyfume 2002

**REFERENCE**

International Organization for Standardization (ISO) 18472, Sterilization of Healthcare Products – Biological and Chemical Indicators – Test Equipment (2006).

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to ISO 13485:2003.

**APPROVAL**

*Trisha E. Fair*  
Trisha E. Fair, B.S.  
Manager, Products

*6-1-09*  
Date