

Gulden Ophthalmics Eye Spheres and Conformers are non sterile. Eye Spheres and Conformers may be sterilized with ethylene oxide (EtO) under the following conditions:

<u>Parameters</u>	<u>Value</u>
Temperature	130 ± 5°F / 54 ± 3°C
Pre-Vacuum	24 - 26 inHg / 610 - 660 mmHg
Relative Humidity	60 ± 10% RH
Humidity Dwell	30 - 45 minutes
Sterilant Gas	100 % EtO
EtO Concentrate	600 ± 30 mg / Liter
Exposure time	2 hours ± 5 minute
Post Vacuum (2 times)	24 - 25 inHg / 610 - 660 mmHg
Mechanical Aeration temperature	110 - 124°F / 43 - 51°C
Residuals after 48 hours minimal Aeration time	EO < 250 ppm ECH < 250 ppm EGly < 5000 ppm
Residuals after 72 hours <b>recommended</b> Aeration time	EO < 250 ppm ECH < 250 ppm EGly < 5000 ppm

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