



## Graver Technologies

### QUALITY CERTIFICATE CERTIFICATE OF CONFORMANCE Citadel™ Filter Elements

Product Construction:	Support Material:	FEP, Expanded PTFE
	Core, Cage, End Caps:	PFA
	Filter Media:	Expanded PTFE
	Filtration Area:	Approximately 7.9 – 8.9 square feet / 10 inches
Manufacturing and Testing Standards:	<ul style="list-style-type: none"><li>• Manufactured, flushed, tested, and packaged in an ISO Class 7 Cleanroom Environment.</li><li>• Filters are 100% flushed with 18 MΩ-cm water and dried.</li><li>• Pre-wet are 100% receive additional flush of 0.2 ppm (minimum) ozonated water</li></ul>	
Operation:	Maximum Operating Temperature:	15 PSID @ 150°C (302°F).
	Rinse-Up Volumes (pre-wet):	18 MΩ-cm in < 5 liters
	Particle Cleanliness (pre-wet):	< 10 particles/mL > 0.1 micron
	Extractable Level (pre-wet):	25 ppb total in 5% HCl
Integrity:	100% by diffusion in 60/40 IPA/Water	

Pore Size	Published DF	Published BP
0.05	≤ 90 cc/min @ 22 psig (1.5 bar)	≥ 28 psig (1.9 bar)
0.1	≤ 50 cc/min @ 18 psig (1.2 bar)	≥ 22 psig (1.5 bar)
0.2	≤ 50 cc/min @ 12 psig (0.8 bar)	≥ 15 psig (1 bar)
0.45	≤ 50 cc/min @ 5 psig (0.34 bar)	≥ 6 psig (0.41 bar)
1.0	≤ 50 cc/min @ 3 psig (0.20 bar)	≥ 4 psig (0.27 bar)
10	N/A	N/A

FDA Listed Materials	All Materials comply with FDA Title 21 of the Code of Federal Regulations Sections 174.5 and 177.1550, as applicable for food and beverage contact.
Endotoxins	During validation, samples were tested and met <0.25 EU/ml which is the current USP requirement for Water for Injection
USP Class VI	All materials meet USP Class VI Biological Test for Plastics.

Expiration Date:	Standard Citadel: 4 years from ship date or 1 year from ship date for pre-wet option providing filters are stored unopened in a dry and ambient environment. Ideal temperature is 25°C.
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This document is to certify that the Citadel Series Filter Elements are produced and distributed according to a Quality Management System that is registered for compliance to EN ISO 9001:2015. All data concerning materials used and production data are documented and accessible under the individual lot number.