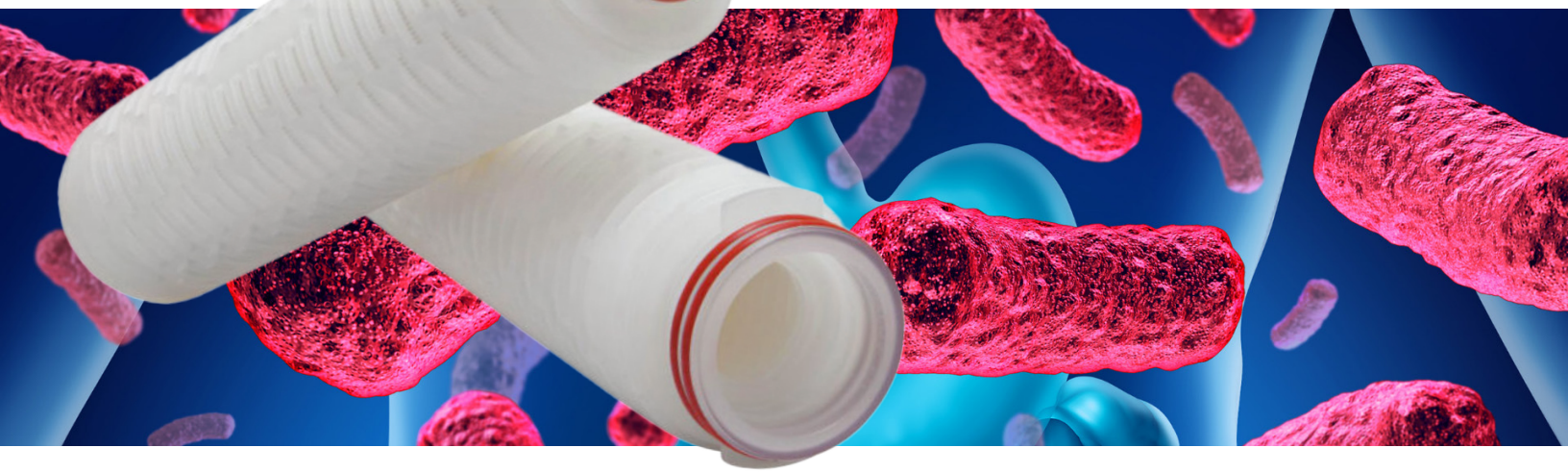
GLOBAL FILTER
Filtration Group®

Ensuring Compliance with ANSI/AAMI ST108

BRHNY+ Series Bio-Burden Reduction Grade Charged Nylon Membrane Filters



As the medical and pharmaceutical industries prepare for the implementation of the ANSI/AAMI ST108 regulations, ensuring compliance with stringent new standards for water quality and filtration is more crucial than ever. Global Filter's BRHNY-Series Bio-Burden Reduction Grade Charged Nylon Plus+ filters offer the perfect solution to meet these demands, providing reliable performance and peace of mind for healthcare facilities, laboratories, and manufacturers.

The BRHNY+ Series Advantage

BRHNY+ Series Bio-Burden Reduction Grade filter cartridges feature Nylon 6,6 membrane with an advanced positively-charged surface modification that is highly effective in capturing submicronic particulate and microbial matter much finer than the stated mechanical rating.

Based on well-documented field use, industry journals, and laboratory data, these characteristics make the BRHNY+ ideally suited for medical device reprocessing applications, where effective removal of microbes and pyrogenic endotoxins is critical to system performance and patient health. Furthermore, the BRHNY+ series presents a more cost-effective alternative to hollow fiber cartridges commonly used for endotoxin/pyrogen removal, while also serving other demanding high-purity applications.

Superior Filtration Performance

The BRHNY-Series filters are designed with advanced Nylon Plus+ membrane technology, offering exceptional bio-burden reduction capabilities. These filters are capable of removing a wide range of contaminants, including bacteria, viruses, and particulates, ensuring the highest levels of water purity required by ANSI/AAMI ST108.

High Flow Rates and Low Pressure Drops

Despite their superior filtration efficiency, BRHNY-Series filters maintain high flow rates and low pressure drops. This ensures that critical operations continue smoothly without compromising on water quality, making them ideal for demanding environments where performance and reliability are critical.

Robust Construction for Extended Service Life

The filters' robust construction guarantees a longer service life, minimizing the frequency of replacements and ensuring consistent compliance with the regulations. The durable design also minimizes downtime and operational disruptions, contributing to overall cost savings.

Compatibility and Easy Integration

Global Filter's BRHNY-Series filters are compatible with a wide range of systems, allowing for easy integration into existing setups. This flexibility means that facilities can upgrade their filtration systems to meet the new ANSI/AAMI ST108 standards without significant modifications or additional investments.

As the deadline for **ANSI/AAMI ST108** compliance approaches, now is the time to upgrade your filtration systems to ensure they meet the new standards. Global Filter's BRHNY-Series Bio-Burden Reduction Grade Nylon Plus+ filters offer the perfect solution, combining superior filtration performance, robust construction, and ease of integration.

Ensure your facility is ready for the future of water filtration. Choose Global Filter's BRHNY+ Series to stay ahead of the curve and continue providing the highest standard of care and product safety.

For more information or to discuss how our solutions can help you achieve compliance, contact Global Filter today.

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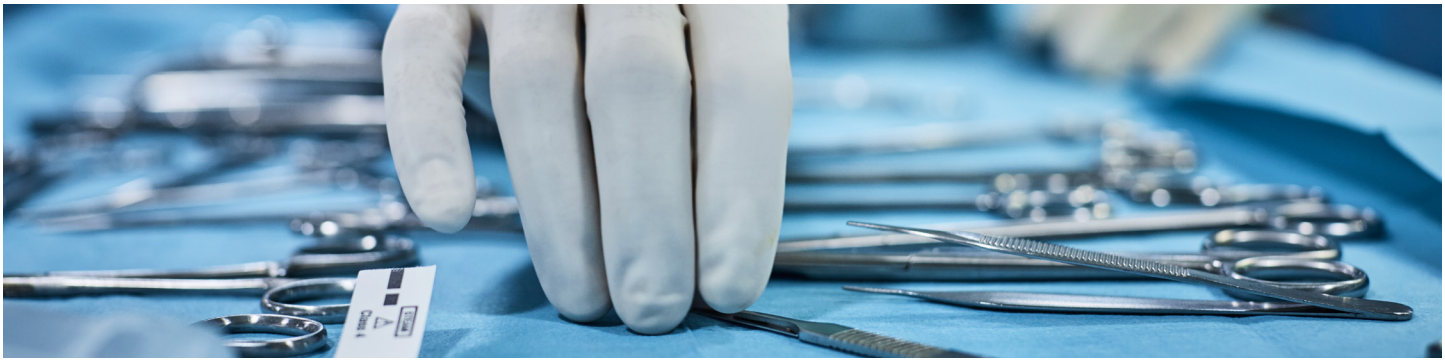
Ensuring Compliance with **ANSI/AAMI ST108**

BRHNY+ Series Bio-Burden Reduction Grade Charged Nylon Membrane Filters



Endotoxin Removal Performance

Bacterial endotoxin is the pyrogen of greatest concern in the pharmaceutical and medical device industries. BRHNY+ filter elements have been proven in independent laboratory testing to remove endotoxins by 100% to non-detectible levels with a challenge concentration of 6.25 Endotoxin Units per milliliter (EU/ml) and a sensitivity of 0.005 EU/ml.

BRHNY+0.05 BIOBURDEN REDUCTION GRADE CHARGED NYLON MEMBRANE - ENDOTOXIN TEST RESULTS	
PARAMETER	**DETAILS**
Challenge Solution	Pyrogen-free water dosed with bacterial endotoxin
Initial Endotoxin Concentration	6.25 EU/mL
Measured Influent Average	3.922 EU/mL
Flow Rate	4 L/min
Total Volume Filtered	20 liters
Number of Cycles	20
Tested Cycles for Endotoxin Retention	Cycles #1, #5, #10, #15, #20
ENDOTOXIN RETENTION	**100% REMOVAL TO BELOW 0.005 EU/ML DETECTION LIMIT**
Total Endotoxin Challenge	Approximately 1.57 x 10^6 EU
Regulatory Compliance	US FDA GMP regulations 21 CFR Parts 210, 211, 820

Endotoxin Test Study Summary

A BRHNY+0.05A10C4S filter was challenged with a solution of pyrogen-free water dosed with 6.25 EU/ml. Twenty liters of challenge solution were pushed through the filter at a flow rate of 4 L/min for 20 total cycles. Influent and effluent samples were collected at defined time points.

The test filters were effective in retaining bacterial endotoxin at a total challenge of approximately 1.57 x 106 EU as demonstrated by all effluent samples being free of endotoxin below the detection limit of 0.005 EU/ml after cycles #1, #5, #10, #15, and #20.

Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211, and 820.

Microbial Retention Performance

Data presented below describes representative results of testing in accordance with the protocol for the evaluation of bacterial retention characteristics of membrane filters. Per the ASTM F858-15a test methodology, each test filter is challenged with a suspension of the referenced microbe, containing at least 1 x 107 colony forming units (CFU) per cm2 of effective filtration area. The sterility of the complete apparatus is tested before the challenge. Each filter is challenged at a pressure of 30 psi. The collected effluent is quantified using 0.45µm assay membranes. Integrity testing is conducted pre- sterilization, post-sterilization, and post-challenge. Testing is performed in compliance with US FDA Good Manufacturing Practice (GMP) regulations 21 CFR Parts 210, 211, and 820.

MICROBE RETENTION EFFICIENCY			
Filter Grade	**Challenge, Typical, CFU/cm**	**Total Challenge, Typical, CFU**	**Log Reduction Value, LRV**
BRHNY+0.1	1.35 X 10^7	9.7 X 10^{10}	>9.1
BRHNY+0.05			>10.1

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