

# Bioflo NY

- Positive Zeta potential
- Enhanced endotoxins retention
- Easy integrity testing in situ
- Repeatedly steamable in situ and in an autoclave
- Thermo-welded construction
- EC-listed materials for Food contact
- FDA-listed materials per 21 CFR
- Bio-Safety per USP - Plastics
- Low filter extractable even with solvents
- Validation Guide available on request



The Bioflo NY filter element is manufactured using a highly positive charged, Nylon 6.6 membrane, its Zeta potential retains negatively charged fine particles even smaller than the pores size itself.

Tests have proven that the positive charged Nylon membrane provides an enhanced retention capability of sub-micron particles and especially on endotoxins in aqueous solution at defined conditions. The intrinsically water wettability of nylon and polyester allows easy integrity testability. Manufacturing is completed in a controlled environment. The filter is easily integrity tested to provide the quality level required in products for pharmaceutical and medical applications.

## Materials of Construction

Filter media	Positive charged nylon 6,6
Upstream supports	Polyester
Downstream supports	Polyester
Internal Core	Polypropylene
External Cage	Polypropylene
End caps / Adapters	Polyester

## Food Safety

BIOFLO NY filter element materials meet (EU) regulation 10/2011 and its amendments, regulations (EC) 1935/2004 and 1895/2005.

## Bio Safety

Filter media and components pass USP CLASS VI Biological reactivity and chemical physical tests for USP plastics.

Specific for PH grade: the filter meets USP "water for injection" requirements for particle release and the effluent is non-pyrogenic per USP bacterial endotoxins (<0,25 EU/ml).

## Quality Standards

Produced under a certified quality system to guarantee traceability of manufacturing records and integrity testing results.

## Operating Conditions

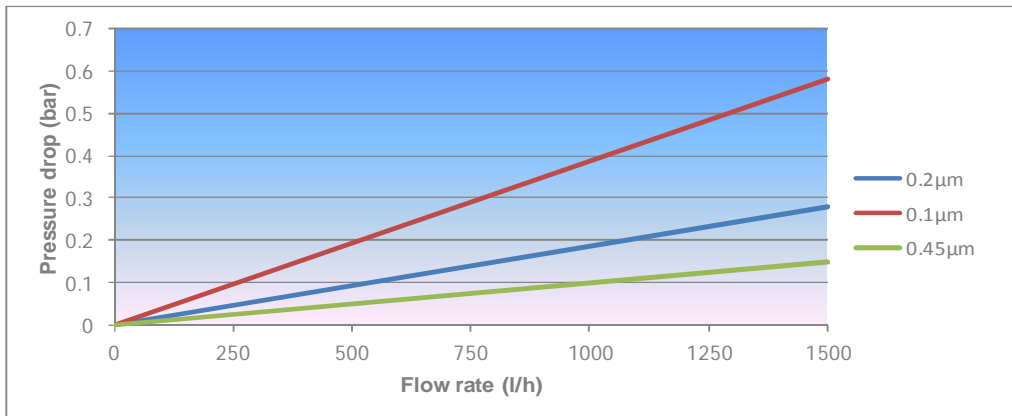
- Maximum continuous temperature of 80°C
- Maximum cumulative time of steam sterilisation is 5 hours at 140°C / 13 hours at 125°C / 20 hours at 121°C
- Sanitisation with hot water is 80°C max
- Sanitisation with chemicals - can be sanitised by standard chemical agents
- Maximum differential pressure is 5.0 bar at 25°C - 2.5 bar 80°C - 0.3 bar 135°C
- Recommended change out differential pressure is 2.0 bar at 25°C
- Recommended rinse up volume is 3 liter / cartridge 10"

ABSOLUTE FILTRATION RATING IN LIQUIDS	BACTERIAL RETENTION OF MICRO-ORGANISM $>10^7$ CFU/10" CARTRIDGE*	ACCEPTABLE LIMIT FOR DIFFUSION FLOW TEST WITH WATER FOR 10" CARTRIDGE (ml/min)
0.1µm	Hydrogenophaga pseudoflava**	≤ 16 @ 2.8 bar
0.2µm	Brevundimonas diminuta	≤ 16 @ 2.1 bar

\*as per ASTM F838-05  
 \*\* bacterial retention with Acholeplasma laidlawii  $\geq 10^7$

**ENDOTOXINS RETENTION IN WATER**  
 350 l/h flow rate / 10" cartridge  
 0.1µm, 0.2µm, 0.45µm

### Water Flow Rate For 10" Cartridge



### Ordering Guide

Name	Micron Rating	Nominal Length	End Cap Type	Seal Type	Special
Bioflo NY	0.1µm	5"	03	S - Silicone	PH - Biological Grade; tested and preflushed with non pyrogenic water.
	0.2µm	10"	04 - DOE	E - EPDM	
	0.45µm	20"	07		
		30"	08		
		40"	28		

V1-08/14



**UK Office:**

Envirogen Water Technologies  
 Charwell House  
 Cheddar Business park  
 Wedmore Road  
 Somerset, BS27 3Eb  
 Tel: +44 (0) 1934 741782  
 E: info@envirogengroup.com  
 www.envirogenwater.com



**Italian Office:**

Fluxa Filtri S.p.A  
 Viale De GASPERI,88/B  
 20017  
 Mazzo di Rho  
 Milano  
 Tel: +39 (0)2 93959.1  
 E: info@fluxafiltri.com  
 www.fluxafiltri.com



**USA Office:**

Envirogen Technologies  
 Two Kingwood Place  
 700 Rockmead Dr. Suite 105  
 Kingwood, TX 77339  
 Tel: +1 877.312.8950  
 E: info@envirogen.com  
 www.envirogen.com